S. HRG. 109–834

FOOD SAFETY: CURRENT CHALLENGES AND NEW IDEAS TO SAFEGUARD CONSUMERS

HEARING

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

UNITED STATES SENATE

ONE HUNDRED NINTH CONGRESS

SECOND SESSION

ON

EXAMINING CURRENT CHALLENGES AND NEW IDEAS TO SAFEGUARD CONSUMERS RELATING TO FOOD SAFETY, FOCUSING ON FOODBORNE ILLNESS IN GENERAL AND THE RESPONSE TO THE RECENT OUTBREAK OF E. COLI INFECTIONS ASSOCIATED WITH FRESH SPINACH

NOVEMBER 15, 2006

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STATEMENTS

WEDNESDAY, NOVEMBER 15, 2006

ADDITIONAL MATERIAL

FOOD SAFETY: CURRENT CHALLENGES AND NEW IDEAS TO SAFEGUARD CONSUMERS

WEDNESDAY, NOVEMBER 15, 2006

U.S. SENATE
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The committee met, pursuant to notice, at 3:00 p.m. in Room SD-430, Dirksen Senate Office Building, Hon. Mike Enzi, chairman of the committee, presiding.

Present: Senators Enzi, Burr, and Isakson.

OPENING STATEMENT OF SENATOR ENZI

The CHAIRMAN. In our tradition of starting on time, I welcome all of you to our hearing on food safety. This kind bears out one of the principles of government. There are a number of other hearings going on right now. This one is very bipartisan. There is a lot of agreement on what has happened, what needs to be done, so consequently, the other committees will be covered better and will draw more Senators. But I want to assure you that the information that we gather today will be utilized by all of the Senators in completing the Agriculture Appropriations bill, making sure that we get it right. They may have questions that will result from the testimony and we will ask that any that testify today answer those questions as promptly as possible so that we can move forward with what is needed to be done.

This is not a partisan issue. We all want our food supply to be as safe as possible. Instead, it's our shared goal that requires cooperation and teamwork through a complicated process that we will examine today. There is a lot of interaction.

For many of us, the safety and reliability of our food system is something we all too often take for granted, day by day, as we consume our favorite beverages, enjoy a quick snack or sit down to a meal at a local restaurant. We rely upon a system of checks and balances that take place behind the scenes that we are often unaware of until something goes wrong.

Then and only then do we realize how dependent we are on the food safety system that is supported by the activities carried out by the Federal, State and local government agencies as well as by the food industry itself. Together they inspect, test, research and monitor our food supply from the farm or ranch where it was produced to the family dinner table where it was consumed. The type and amount of oversight they exercise depends on the food product

and the degree of regulatory scrutiny they demand is commensurate with the degree of risk.

Today's hearing will take a close look at the recent *E. coli* outbreak associated with bagged spinach and help us understand how it was identified, tracked and ultimately contained. We'll hear about interagency coordination and the cooperation of Federal and State officials during the outbreak. We'll also be examining some new and exciting technologies that could help limit future outbreaks or even prevent them.

The Centers for Disease Control and Prevention, the CDC, estimates that foodborne illnesses affect 76 million Americans each year, which results in 325,000 hospitalizations and possibly 5,000 deaths. Food-borne illnesses also impose tremendous costs on the U.S. economy. The Department of Agriculture estimates costs associated with medical expenses, premature death and losses in productivity due to missed work from five major types of foodborne illnesses to be $6.9 billion annually. At the Federal level, within the Department of Agriculture, the Food Safety and Inspection Service regulates meat, poultry and processed egg products. Additional agencies in the Department of Agriculture support research on food safety and the economics of foodborne illness and ensure the safety of foods distributed through school nutrition programs.

The Food and Drug Administration, Centers for Disease Control and Prevention and the National Institutes of Health, all housed within the Department of Health and Human Services and under the jurisdiction of this committee, play important roles in food safety. Two centers in the Food and Drug Administration, the Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine, ensure that all food produced domestically or imported, other than meat, poultry and processed eggs, is safe and that drugs given to animals raised to be used for human food do not cause health problems for humans. The Centers for Disease Control and Prevention tracks foodborne incidents and outbreaks and provides data and information to the other food safety agencies, while the National Institutes of Health is responsible for research on the health effects of foodborne illnesses and the effectiveness of possible treatments.

Finally, the Office of Pesticide Programs of the Environmental Protection Agency is responsible for setting tolerances, the limit of the amount of residues from chemicals that can be found in or on food and for promoting safer means of test management and the National Marine Fishery Service at the Department of Commerce provides fishery inspection services.

In addition to these longstanding authorities and activities in food safety, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 required the Food and Drug Administration to register food processors, inspect their records and detain adulterated food. It also requires the Food and Drug Administration to issue regulations to ensure the safety of imported foods.

Despite all this, food safety has been making the news lately. Late this summer, reports of an outbreak of illness due to a strain of *E. coli* bacteria began trickling in to State and Federal agencies. By the time the outbreak ended, there were 204 confirmed cases in 26 States that resulted in three deaths. The outbreak was ulti-

mately traced to bagged spinach from the Nation's salad bowl, a valley in California. The long-term effects of this outbreak on the spinach industry in California and across the Nation, as well as on consumer confidence in food safety, are not yet known. Just last month, the Centers for Disease Control began investigating a salmonella outbreak, which was traced back to tomatoes served at restaurants. Twenty-one States have reported 183 cases of illness due to these tomatoes. Food-borne illnesses associated with produce are particularly difficult to manage since the source of the illness is perishable and the product is likely to be consumed or thrown out before an illness becomes apparent.

The United States has one of the best food safety systems in the world but even in the best of systems, there is always room for improvement. Those improvements can take many forms. For example, we can address how food becomes contaminated in the first place and we can make advances in the processing and the handling of food. Our surveillance testing and reporting systems represent areas we should evaluate as well as internal and external communications. Interagency coordination and cooperation between Federal and State officials is critical in identifying, tracking and responding to outbreaks of foodborne illnesses. I am particularly interested today in hearing how Federal and State agencies work together during an outbreak to assess and respond to a situation and how government at all levels communicates with the public.

Finally, there is always new science. Tests to assist with diagnosis and treatment can be made faster and better. Improvements in processing, handling and traceability have potential to radically alter the landscape of potential risk. There will always be new and emerging foodborne pathogens that need to be identified. Our goal is always to be proactive rather than reactive in these situations. No one innovates like small business, and as we will hear later today, there is no shortage of companies with great new ideas to improve food safety.

We'll hear first from Dr. Robert Brackett, the Director of the Center for Food Safety and Applied Nutrition at the Food and Drug Administration and Dr. Lonnie King, the Senior Veterinarian at the Centers for Disease Control and Prevention. I would note that Senator Kennedy has a scheduling conflict and is not here for an opening statement but he has asked that one be submitted for the record and it will be.

[The prepared statement of Senator Kennedy follows:]

PREPARED STATEMENT OF SENATOR KENNEDY

Thank you, Mr. Chairman, and I commend you for calling this hearing on the safety of America's food.

You've arranged today's hearing with the same consideration and courtesy that have been the hallmark of your chairmanship. Your bipartisanship is a major reason why the committee has worked so effectively over the past 2 years on many problems affecting America's families, and it is the spirit in which the committee will continue to do business in the next Congress.

In a few weeks, many of us will travel home to join our loved ones for a Thanksgiving meal that celebrates family, community,

and our gratitude for the bounty that God has bestowed on our Nation.

We too often take it for granted that the food we eat is safe and free from dangerous contamination. Recent outbreaks of *E. coli* [EE-coal-eye] and *Salmonella* have shown all too clearly that network of protections we count on to protect us from deadly foodborne illness is a frayed and inadequate patchwork.

These outbreaks are examples of a wider problem with food safety. According to the CDC, there are 76 million cases of foodborne illness every year. Most of them result only in mild symptoms, but diseases caused by contaminated food cause over 325,000 hospitalizations and 5,000 deaths every year, which means that an average of 13 Americans die from a foodborne illness every day.

A few weeks ago, spinach contaminated with a deadly strain of *E. coli* made its way from farms in California into the food supply, and quickly spread to 26 States. When the outbreak was finally over, 204 individuals were infected, 102 were hospitalized, and 3 died.

The deaths of a 2-year-old boy in Idaho and two elderly women in Wisconsin and Nebraska highlight the special vulnerability of children and seniors to these illnesses.

Many dedicated professionals in local, State and Federal health agencies worked hard to respond to these outbreaks—but *responding* to an outbreak means that the battle is already lost. We need to learn what must be done to *prevent* these outbreaks from occurring in the first place.

In November 2005—months before the recent outbreak—FDA had sent a letter to California vegetable firms outlining "serious concerns with the continuing outbreaks of foodborne illnesses associated with the consumption of fresh and fresh-cut lettuce and other leafy greens." That November letter wasn't even the first warning by FDA. It reiterated concerns in a letter 9 months earlier.

Despite these repeated warnings, corrective actions were not taken to prevent the subsequent outbreak. Obviously, we need to strengthen our approach to food safety.

The questions are many. Does FDA need additional authority to take action when problems are identified? Does it have the authority but lack the resources to take action? Is coordination adequate among Federal agencies, and between Federal and State agencies, so that prompt action can be taken when problems are detected?

Not every outbreak is foreseeable or preventable. But when there are persistent problems that have not been corrected, it is the responsibility of Congress to set things right, and that's the purpose of this hearing.

We'll also hear today from representatives of firms with new technologies to improve food safety, through better detection of contamination and better ways to trace the flow of food products from farm to table. I look forward to their testimony, and to the testimony of representatives from our Federal and State health agencies. We're all partners in the effort to see that the food that American families eat is safe from contamination and danger.

The CHAIRMAN. So if I could have Dr. Brackett and Dr. King take their places at the table.

I would like to welcome Dr. Robert Brackett, who is the Director for the Center for Food Safety and Applied Nutrition at FDA and Dr. Lonnie King, the Senior Veterinarian at the CDC. Dr. Brackett will discuss FDA's role in identifying, tracking and containing the recent outbreak of *E. coli* associated with the bagged spinach and Dr. King will do the same for the CDC's efforts. We appreciate your being here today and we will begin with Dr. Brackett.

STATEMENT OF DR. ROBERT BRACKETT, DIRECTOR, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION, ROCKVILLE, MD

Dr. BRACKETT. Good afternoon, Chairman Enzi and Senator Burr. I am Robert E. Brackett, Ph.D., Director of the Center for Food Safety and Applied Nutrition at the Food and Drug Administration, which is part of the Department of Health and Human Services.

I would like to thank you for this opportunity to discuss food safety and the recent outbreak of *E. coli* O157:H7 that was linked to fresh spinach. I am also pleased to be here today with my colleague, Dr. Lonnie King, from the CDC.

FDA is the Federal agency that regulates everything we eat except for meat, poultry and egg products, which are regulated by our partners at USDA. FDA's responsibility also extends to the live food animals and animal feed.

Ensuring the safety of the food supply continues to be a top priority at FDA and the Administration and in recent years, we have done a great deal to protect the food supply from unintentional contamination as well as deliberate contamination and we have made significant progress in both. But we will continue to strive to reduce the incidence of foodborne illness to the lowest level possible. However, the recent *E. coli* outbreak shows that further progress is needed, particularly with ready-to-eat produce.

Ready-to-eat fresh vegetables, fruits and prepared salads have a high potential risk of contamination because they are generally grown in the natural environment such as a field or orchard and are often consumed without cooking or other treatments that could eliminate pathogens that might be present. The number of illnesses associated with fresh produce is a continuing concern of the agency and we have worked on a number of initiatives to reduce the presence of pathogens in these foods and I will describe some of these initiatives later in my testimony.

First I'd like to briefly describe FDA's actions in response to the recent outbreak.

On the afternoon of September 13, the CDC informed FDA of a multi-state foodborne outbreak of *E. coli*, O157:H7 possibly associated with the consumption of fresh spinach. The next day, on September 14, the CDC notified FDA that the epidemiological data confirmed that fresh spinach was implicated as the source of the illnesses. That day, FDA, CDC, the State of California and other State officials began holding daily conference calls to share information, coordinate efforts to contain the spread of the outbreak, and investigate the cause.

Also on September 14, FDA took immediate action to prevent further illness by alerting consumers and initiating an investiga-

tion. FDA's San Francisco district office and California Department of Health Services Food and Drug branch hosted a conference call with three spinach-processing firms in the Salinas area of California. We informed these firms that FDA would begin onsite investigations of processing facilities on that day.

The response to the recent outbreak of *E. coli* is a good example of the close and effective working relationships that we enjoy with our food safety partners. The daily conference calls with FDA, CDC and the State officials were a vital and efficient means for sharing information, coordinating efforts to contain the spread of the outbreak and investigating the cause. This constant communication also enabled the Federal and State agencies to coordinate their public health messages for consumers. As I mentioned earlier, FDA continues to be concerned about the number of foodborne illness outbreaks associated with fresh produce. In recent years, FDA has initiated several activities to address these concerns and some of these activities include developing new guidance, conducting outreach to consumers, sampling and analyzing both domestic and imported produce for pathogens and working with the produce industry to promote the use of good growing, harvesting, packing, transporting and processing practices. In October 2004, FDA announced a major initiative, the Produce Safety Action Plan, to help reduce the incidence of foodborne illness attributed to produce. As part of the Produce Safety Action Plan, the FDA has provided technical assistance to the produce industry in developing guidance for five specific commodity groups, that being cantaloupes, lettuce and leafy greens, tomatoes, green onions, and herbs. We are also working in a broader context to address the food safety concerns for all leafy greens.

In the past 2 years, FDA twice wrote to the industry to express FDA's concern with continuing illness outbreaks and to express our expectations for industry to enhance the safety of these products. More recently, in August 2006, FDA and the State of California launched the Lettuce Safety Initiative to reduce public health risks associated with fresh and fresh-cut lettuce and leafy greens. In view of the recent *E. coli* O157:H7 outbreak and after discussions with the industry, FDA and the State of California advised the industry to develop a plan to minimize the risk of another outbreak of all leafy greens, including lettuce.

FDA, CDC and the State of California and the USDA continue to investigate the cause of the outbreak and once we've completed that investigation, FDA will hold a public meeting to address the larger issue of foodborne illness linked to leafy greens. As part of our evaluation, we will consider whether additional guidance and/or additional regulations will be necessary.

In conclusion, FDA is working hard in collaboration with our Federal, State, local and international safety partners and with the industry, consumers and academia to improve the safety of fresh produce. We have made significant progress but will continue to strive to reduce the incidence of foodborne illness to the lowest level possible. Again, I thank you for the opportunity to discuss FDA's Food Safety Programs and I'd be happy to answer any questions.

[The prepared statement of Dr. Brackett follows.]

PREPARED STATEMENT OF ROBERT E. BRACKETT, PH.D.

INTRODUCTION

Good afternoon, Chairman Enzi and members of the committee. I am Dr. Robert Brackett, Director of the Center for Food Safety and Applied Nutrition (CFSAN) at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). I am pleased to be here today with my colleague, Dr. Lonnie J. King, from the Centers for Disease Control and Prevention (CDC), which is also part of HHS. FDA appreciates the opportunity to discuss the recent outbreak of *Escherichia coli* (*E. coli*) O157:H7 linked to fresh spinach and the lessons learned from this outbreak.

Ensuring the safety of the food supply continues to be a top priority for FDA and the Administration. In recent years, we have done a great deal to protect the food supply from unintentional contamination and from deliberate contamination. We have made significant progress in both, but will continue to strive to reduce the incidence of foodborne illness to the lowest level possible.

A recent report (April 2006) issued by CDC, in collaboration with FDA and the U.S. Department of Agriculture (USDA), shows that progress has been made in reducing foodborne infections. This report provided preliminary surveillance data that show important declines in foodborne infections due to common pathogens in 2005 when compared against baseline data for the period 1996 through 1998. The report showed that the incidence of infections caused by *Campylobacter*, *Listeria*, *Salmonella*, Shiga toxin-producing *E. coli* O157, *Shigella*, and *Yersinia* has declined. *Campylobacter* and *Listeria* incidence are approaching levels targeted by national health objectives. This report shows that FDA's and USDA's efforts are working, and we are making progress. However, the recent *E. coli* outbreak shows that further progress is needed, particularly with ready-to-eat produce.

Ready-to-eat fresh vegetables, fruits, and prepared salads have a high potential risk of contamination because they are generally grown in a natural environment (for example, a field or orchard) and are often consumed without cooking or other treatments that could eliminate pathogens if they are present. The number of illnesses associated with fresh produce is a continuing concern of the Agency, and we have worked on a number of initiatives to reduce the presence of pathogens in these foods.

In my testimony today, I will first explain FDA's role in food safety. Then, I will discuss FDA's response to the recent *E. coli* outbreak and the ongoing investigation. I also will describe some of the specific efforts that FDA is taking to enhance the safety of fresh produce to prevent future outbreaks. Finally, I will review some of the next steps we plan to take to work with our food safety partners to improve the safety of these foods.

FDA'S ROLE IN FOOD SAFETY

FDA's primary mission is to protect the public health. Ensuring that FDA-regulated products are safe and secure is a vital part of that mission. FDA is the Federal agency that regulates everything we eat except for meat, poultry, and processed egg products, which are regulated by our partners at USDA.

Although FDA has the lead responsibility within HHS for ensuring the safety of food products, CDC has an important complementary and nonregulatory public health role. CDC is the lead Federal agency for conducting disease surveillance and outbreak investigation and routinely monitors the occurrence of specific illnesses in the United States attributable to the entire food supply. The disease surveillance systems coordinated by CDC, in collaboration with States, provide an essential early-information network to detect dangers in the food supply and to reduce foodborne illness. Two key surveillance components of our Nation's early information network are PulseNet and OutbreakNet. PulseNet is a national network of public health laboratories that perform DNA fingerprinting on foodborne bacteria that result in human illness. The PulseNet network permits rapid comparison of these fingerprint patterns through an electronic database at CDC. OutbreakNet is a network of public health epidemiologists who, under CDC's coordination, investigate suspected foodborne disease outbreaks to determine which foods may be involved and, thus, which control strategies may be needed. Both of these networks provided important information that led to the early detection of the recent outbreak. CDC's ability to detect and investigate outbreaks of foodborne illness through its networks enable CDC to alert FDA and USDA about implicated food products associated with foodborne illness. CDC also provides expert scientific evaluations of the effectiveness of foodborne disease prevention strategies.

FDA contributes financially and scientifically to the Foodborne Diseases Active Surveillance Network (FoodNet), the principal foodborne disease component of CDC's Emerging Infections Program (EIP). FoodNet is a collaborative activity of CDC, FDA, the Food Safety and Inspection Service (FSIS) of USDA, and 10 EIP sites. Through this active surveillance system, these sites actively seek out information on foodborne illnesses identified by clinical laboratories, collect information from patients about their illnesses, and conduct investigations to determine which foods are linked to specific pathogens. This surveillance system provides important information about changes over time in the burden of foodborne diseases. For example, the CDC foodborne illness report I mentioned earlier used data from FoodNet to identify the decline in the incidence of specific foodborne illnesses. These data help public health and food safety agencies evaluate the effectiveness of current food safety initiatives and develop and plan future food safety activities to prevent and reduce emerging foodborne illnesses. My colleague here today from CDC will provide additional details about CDC's important public health programs.

In addition to working closely with CDC, our sister public health agency, FDA has many other food safety partners—Federal, State, and local agencies; academia; and industry. The Government's response to the recent *E. coli* outbreak is a good example of the close and effective working relationships we enjoy with our food safety partners.

RECENT E. COLI O157:H7 OUTBREAK LINKED TO FRESH SPINACH

On the afternoon of September 13, CDC informed FDA of a multi-state foodborne illness outbreak, that appeared to be ongoing, of *E. coli* O157:H7 possibly associated with the consumption of fresh spinach. On September 14, CDC notified FDA that the epidemiological data confirmed that fresh spinach was implicated as the source of the illnesses. That day, FDA, CDC, and California and other State officials began holding daily conference calls to share information, coordinate efforts to contain the spread of the outbreak, and investigate the cause.

Also that day, FDA's San Francisco District Office and California Department of Health Services' Food and Drug Branch hosted a conference call with three spinach-processing firms to advise them of the outbreak and to suggest that they consider the possible need to recall spinach products. We informed these firms that FDA would begin onsite investigations of processing facilities that day. FDA, in conjunction with the California Food and Drug Branch, also activated the California Food Emergency Response Team (CalFERT), a joint California and FDA response team to investigate the source of *E. coli* O157:H7 and determine the extent of possibly contaminated product.

Once CDC notified FDA that they had confirmed that fresh spinach was the source of the outbreak, FDA immediately took action to prevent further illnesses by alerting consumers. On September 14, FDA held a press teleconference and issued a press release alerting consumers about the outbreak, stating that preliminary epidemiological evidence suggested that bagged fresh spinach may be the cause and advising consumers to avoid bagged fresh spinach. Over the course of the next few days, the advisory was expanded to include all fresh spinach to ensure that consumers could adequately avoid eating any tainted product. This revision to the initial advisory became necessary when we learned that bagged spinach was sometimes sold in an un-bagged form at the retail level. This revised advisory remained in effect until September 22, when we were confident that the source of the tainted spinach was restricted to the three implicated counties in California. At that time, we advised consumers that spinach from outside these counties was not implicated in the outbreak and could be consumed.

During the outbreak, on an almost daily basis, FDA held press conferences (that included spokespersons from the State of California), issued press releases, and posted updates on our Website to limit the spread of the outbreak by keeping the public informed. FDA also worked closely with foreign government's food safety officials to provide them up-to-date information regarding the recall.

FDA, the State of California, CDC, and the USDA continue to investigate the cause of the outbreak. The environmental and onsite investigation has included inspections and sample collection in facilities, the environment, and water. In addition, investigators have reviewed and evaluated animal management practices, water use, and the environmental conditions that could have led to contamination of the spinach. The field investigation team has included experts in multiple disciplines from FDA, CDC, USDA, and the State of California.

The joint FDA/State of California field investigation found the same strain of *E. coli* O157:H7 as was involved in the illness outbreak in samples taken from a stream and from feces of cattle and wild pigs present on ranches implicated in the

outbreak. The investigation team also found evidence that wild pigs have been in the spinach fields. We continue to look for more information as to the source and mechanism of contamination.

FDA INITIATIVES TO ENHANCE SAFETY OF PRODUCE

As I mentioned earlier, FDA continues to be concerned about the number of foodborne illness outbreaks associated with fresh produce. In the past decade, consumption of produce, particularly "ready-to-eat" products, has increased dramatically. These products are usually consumed in their raw state without processing to reduce or eliminate pathogens that may be present. Consequently, the manner in which they are grown, harvested, packed, processed, and distributed is crucial to ensuring that microbial contamination is minimized, thereby reducing the risk of illness to consumers.

FDA has initiated several activities to address safety concerns associated with the production of fresh produce in response to the increase in illnesses associated with consumption of fresh produce. Some of these activities include: developing guidance, conducting outreach to consumers, sampling and analyzing both domestic and imported produce for pathogens, and working with industry to promote the use of good growing, harvesting, packing, transporting, and processing practices.

In 1998, FDA and USDA issued guidance for industry, "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables." This guidance, known as the Good Agricultural Practices (GAPs) guidance, addresses microbial food safety hazards and good agricultural and management practices common to the growing, harvesting, washing, sorting, packing, and transporting of most fruits and vegetables sold to consumers in an unprocessed or minimally processed (raw) form. FDA and USDA issued the guidance in several languages and have conducted significant outreach, both domestically and internationally, to encourage its implementation.

After raw sprouts were associated with several outbreaks, FDA issued two guidance documents in 1999 for the sprout industry. The guidance documents contain steps that the sprout industry could use to reduce microbial hazards common to sprout production to ensure that sprouts are not a cause of foodborne illness. Implementation of the guidance has reduced the incidence of outbreaks of illness attributed to the consumption of sprouts.

Since then, FDA has collaborated with industry, in cooperation with State agencies and academia, to develop commodity-specific supply chain guidance for the commodities most often associated with foodborne illness outbreaks. FDA contracted with the Institute of Food Technologists (IFT) to summarize scientific research relating to the various methods of eliminating or reducing pathogens on whole and fresh-cut produce. The 2001 report generated as part of the contract with IFT provided important information that we used to plan and develop future produce safety activities.

In October 2004, FDA announced its Produce Safety Action Plan to help reduce the incidence of foodborne illness attributed to the consumption of produce. The Action Plan has the following four objectives: (1) preventing contamination of fresh produce with pathogens; (2) minimizing the public health impact when contamination of fresh produce occurs; (3) improving communications with producers, preparers and consumers about fresh produce safety; and (4) facilitating and supporting research relevant to fresh produce. This Plan represents the first time that FDA had developed a comprehensive food safety strategy specific to produce.

Since 2005, as part of the Produce Safety Action Plan, FDA has provided technical assistance to industry in developing guidance for five commodity groups: cantaloupes, lettuce and leafy greens, tomatoes, green onions, and herbs. These commodities account for more than 80 percent of the foodborne outbreaks associated with produce. Three of the guidance documents (for cantaloupes, tomatoes, and lettuce and leafy greens) have been completed. We have recently made these guidance documents available, and FDA has done outreach and training with the industry to implement the guidance. FDA is still working on the commodity-specific guidance for herbs and green onions. In March of this year, we released draft guidance for the fresh-cut produce industry, "Draft Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables." We are currently working to finalize this guidance document.

In August 2006, FDA met with Virginia officials to discuss outbreaks associated with tomatoes produced on the eastern shore of Virginia. FDA is working with the Florida Tomato Exchange and the University of Florida's Institute of Food and Agricultural Sciences to arrange a forum to discuss ways to improve the safety of tomatoes. The preliminary plan is for the forum to include FDA, State officials including Commissioners of Agriculture and Secretaries of Health, as well as representatives

from institutions and industry in several selected States. Once our investigation of the recent *Salmonella Typhimurium* outbreak linked to fresh tomatoes served in restaurants is complete, we will also re-examine the need for additional safety measures to ensure tomato safety.

We also are working in a broader context to address food safety concerns for all leafy greens. In the past 2 years, FDA twice wrote to industry to express FDA's concerns with continuing illness outbreaks and to express our expectations for industry to enhance the safety of these products. These letters were a "Notice to Firms that Grow, Pack, or Ship Fresh Lettuce and Fresh Tomatoes" sent in February 2004 and a "Letter to California Firms that Grow, Pack, Process, or Ship Fresh and Fresh-cut Lettuce" (and leafy greens) sent in November 2005.

More recently, in August 2006, FDA and the State of California launched the Lettuce Safety Initiative at the "Forum for Discussion of Lettuce Safety," hosted by the Western Institute for Food Safety and Security (WIFSS). This initiative was developed as a response to the recurring outbreaks of *E. coli* O157:H7 associated with fresh and fresh-cut lettuce and leafy greens, primarily, but not exclusively, from the Salinas Valley area. The multiyear initiative is intended to reduce public health risks by focusing on the product, agents, and areas of greatest concern. The four objectives of the proactive initiative are to: (1) assess current industry approaches and actions to address the issue of improving lettuce safety and, if appropriate, stimulate segments of the industry to further advance efforts in addressing all aspects of improving lettuce safety; (2) alert consumers early and respond rapidly in the event of an outbreak; (3) obtain information for use in developing and/or refining guidance and policy that will minimize future outbreaks; and (4) consider regulatory action, if appropriate.

Through its investigations of farms implicated in previous outbreaks, FDA has identified many possible factors that contribute to the contamination of fresh produce. These factors include the exposure of produce to poor quality water, manure used for fertilizer, workers with poor hygiene, and animals, both domesticated and wild, on the farm. FDA has been working with the State of California and the industry to promote the adoption of measures to prevent contamination of fresh produce.

NEXT STEPS

In view of this recent *E. coli* O157:H7 outbreak, and after discussions with industry, FDA and the State of California advised the industry to develop a plan to minimize the risk of another outbreak in all leafy greens, including lettuce. Once we have completed our current investigation, FDA will hold a public meeting to address the larger issue of foodborne illness linked to leafy greens. We will also be examining whether improvements in the following four areas could help prevent or contain future outbreaks: (1) strategies to prevent contamination; (2) ways to minimize the health impact after an occurrence; (3) ways to improve communication; and (4) specific research. We also will be holding a series of meetings with industry groups to discuss ways to improve the safety of fresh produce. As part of our evaluation, we will consider whether additional guidance and/or additional regulations are necessary.

As we continue to look for a better path to improving the safety of fresh produce, research will remain a critical element. This element of a critical path to safer foods will need to include research on analytical technologies that enable faster detection of foodborne pathogens and better intervention strategies. Our current research agenda is focused on improving the identification and detection of disease-causing bacteria and toxins in a variety of foods. More rapid and precise testing methods are important to minimizing the spread of foodborne disease once it occurs. We are also studying possible intervention strategies, such as use of thermal treatment and irradiation, which could be applied to fresh produce products to reduce the level of bacteria and viruses that are in or on the product.

In addition, we are working with universities, industry, and State governments to develop both risk-based microbiological research programs and technology transfer programs to ensure that the latest food technology reaches the appropriate end users along the supply chain. We will continue to work with these partners to develop guidance, conduct research, produce educational outreach documents, and to initiate other commodity- or region-specific programs that will enhance the safety of fresh produce.

CONCLUSION

In conclusion, FDA is working hard, in collaboration with its Federal, State, local, and international food safety partners and with industry, consumers, and academia,

to improve the safety of fresh produce. As a result of this effective collaboration, the American food supply continues to be among the safest in the world. This year's report of FoodNet data clearly shows that the preventive measures being implemented by FDA, USDA, and others are achieving significant public health outcomes in the effort to reduce the incidence of foodborne illness. We have made significant progress but will continue to strive to reduce the incidence of foodborne illness to the lowest level possible.

Thank you for the opportunity to discuss FDA's food safety programs. I would be happy to answer any questions.

The CHAIRMAN. Thank you, Dr. Brackett.

Dr. King.

STATEMENT OF DR. LONNIE KING, SENIOR VETERINARIAN, CENTERS FOR DISEASE CONTROL AND PREVENTION, ATLANTA, GA

Dr. KING. Thank you, Chairman Enzi and Senator Burr. Good afternoon. I am pleased to be here to discuss CDC's activities related to foodborne illness and our role in the response to the recent outbreak of *E. coli* infections associated with fresh spinach.

Many people do not think about food safety until food-related illness affects them or a member of their family. The Chairman talked about the estimates that CDC has, of 76 million people getting sick every year, more than 300,000 hospitalizations and perhaps as many as 5,000 deaths each year due to foodborne illness. So preventing foodborne illness remains a major public health challenge.

CDC leads Federal efforts to gather data on foodborne illnesses, to investigate illnesses and outbreaks and monitor the effectiveness of prevention and controls efforts. CDC is not a food safety regulatory agency but it works closely with our regulatory colleagues and in particular with the FDA and the USDA. CDC also plays a key role in identifying prevention strategies, building State and local health departments and supporting epidemiology, laboratory in an environmental health capacity in order to support foodborne illness surveillance and outbreak response.

Notably, CDC data are used to help document the effectiveness of regulatory interventions and to develop new preventive strategies.

Routine disease surveillance systems coordinated by CDC provide an essential early information network to detect potential threats to our public's health. These systems can be used to indicate new or changing patterns of foodborne illness. For example, PulseNet is the national network for DNA fingerprinting of foodborne bacteria, which was developed in collaboration with the Association of Public Health Laboratories and is coordinated by the CDC. The laboratories participating in PulseNet are in the State health departments and some local health departments.

PulseNet plays a vital role in surveillance for investigations of foodborne illness outbreaks that were previously very difficult or impossible to detect. The strength of this system is its ability to rapidly detect a cluster of infections and identify DNA patterns, even if the infected persons are geographically far away, as we saw in this outbreak. It is very important to have this mechanism, given the reality of our foodborne distribution systems today.

During the recent *E. coli* outbreak related to spinach, PulseNet was critical to identifying this outbreak. In early September, PulseNet showed that the DNA patterns in clusters in Wisconsin and Oregon were identical and that other States reported cases with the same PulseNet pattern among ill persons who had also eaten fresh spinach. Rapid collection of standard case exposure information by epidemiologists in these affected States and the sharing of exposure information among States and the CDC led to the rapid identification of the suspected food source and a public health action.

Quick sharing of information among the States, CDC and FDA led to a warning to the public on September 14, not to eat fresh bagged spinach. Coordination with the FDA was essential for investigating this outbreak. Frequent conference calls relayed the data on spinach purchases and sources through FDA, guiding and helping with the ongoing investigation. At FDA's request, an experienced hydrologist from CDC's National Center for Environmental Health, was deployed to California to join the FDA and the California Food Emergency Response Team in the investigation of possible environmental sources of contamination that led to this outbreak.

To ensure that the information was disseminated to the public as accurately and quickly as possible about the health threats and other information related to this outbreak, CDC and the FDA coordinated their communications strategies and their messages, discussed these strategies in daily conference calls and also included State health officials.

CDC's daily posting of case updates ended on October 6 when it was clear that the outbreak was over, although PulseNet continues to monitor the frequency of this pattern of *E. coli* O157 infections.

In conclusion, this event and the more recent salmonella outbreak related to tomatoes illustrates how large and widespread outbreaks can occur, appearing first as a small cluster and then rapidly increasing if a popular commercial product has been contaminated. It also illustrates the importance of existing public health networks, the laboratories performing PulseNet fingerprinting, and the epidemiologists, who interview patients and look at healthy people and make the comparisons and collect leftover produce. The multidisciplinary approach needed for such investigations and the close communication and collaboration among local, State and Federal officials, without question, a rapid and action analysis of and response to an outbreak will result in the prevention of exposure to contaminated products and will stop further illness and death, which happened in this case. Produce-related outbreaks are a growing challenge to public health as the *E. coli* and other outbreaks indicate. Research should focus on tracing the specific pathways that connect fields of leafy green vegetables with potential animal reservoirs of *E. coli* and other disease-causing microbes.

CDC is prepared to continue working with regulatory authorities, food and environmental microbiologists and the food industry to find long-term solutions to this very challenging problem. Thank you for highlighting this very important public health issue and Dr.

Chris Braden and I are very happy to answer any questions you might have.

[The prepared statement of Dr. King follows:]

PREPARED STATEMENT OF LONNIE J. KING, D.V.M.

INTRODUCTION

Good afternoon, Chairman Enzi and members of the subcommittee. I am Lonnie King, the Centers for Disease Control and Prevention's (CDC) senior veterinarian, and I am leading the effort to form a new center at CDC focusing on zoonotic, vector-borne, and enteric diseases, which includes CDC's foodborne illness-related activities. Accompanying me today is Dr. Chris Braden, Chief of the Outbreak Response and Surveillance Team for our foodborne illness activities. Thank you for the invitation to address the subcommittee on CDC's activities related to foodborne illness in general and on CDC's role in the response to the recent outbreak of *E. coli* infections associated with fresh spinach.

BACKGROUND

Many people do not think about food safety until a food-related illness affects them or a family member. CDC estimates that 76 million people get sick, more than 300,000 are hospitalized, and 5,000 Americans die each year from foodborne illness. Preventing foodborne illness remains a major public health challenge.

More than 250 different foodborne illnesses have been described in scientific literature. Most of these diseases are caused by a variety of bacteria, viruses, and parasites. Some foodborne illnesses are poisonings, caused by harmful toxins or chemicals that have contaminated the food such as those found in poisonous mushrooms. These various illnesses have many different clinical signs, and therefore they cannot be characterized as one foodborne illness "syndrome."

Microbes spread in a variety of ways, so it is not always certain that an identified illness is caused by food. In order to prevent and control illness, public health authorities need to determine how a particular disease is spreading. For example, *Escherichia coli* (*E. coli*) O157:H7 infections can spread through contaminated food, contact with infected petting zoo animals, contaminated swimming water, and from toddler to toddler at a childcare center. Depending on transmission routes, the measures to stop other cases from occurring might involve removing contaminated food from stores, chlorinating a swimming pool, or closing a childcare center. By conducting a rapid investigation, epidemiologists and laboratorians can determine the source of an outbreak and recommend immediate measures to control it. Detailed investigations into how contamination occurs are critical to developing strategies to prevent similar outbreaks in the future.

Many foodborne infections occur separately without obvious connection to other cases. These are called sporadic cases. Determining the source of a single sporadic case can be very difficult. Cases of similar infections can also occur as a group or "cluster." Epidemiological investigation of clusters of possibly related cases permits public health officials to determine if the cases are linked to food, which is the first step in preventing further illnesses. An outbreak of foodborne illness is considered a cluster if two or more infections caused by the same agent (pathogen or toxin) are linked to the same food upon investigation. Roughly 1,200 foodborne outbreak investigations are reported to CDC each year. CDC works closely with local and State health departments to investigate foodborne disease outbreaks and make information available to the public.

Produce-related outbreaks such as the recent outbreak associated with raw spinach have become larger and more common. For example, in the 1970s, foodborne outbreaks related to produce accounted for less than 1 percent of outbreaks with a known food source. By the end of the 1990s, they accounted for 6 percent of these outbreaks.

CDC'S ROLE IN PREVENTING FOODBORNE ILLNESS

As an agency within the Department of Health and Human Services (HHS), CDC leads Federal efforts to gather data on foodborne illnesses, investigate foodborne illnesses and outbreaks, and monitor the effectiveness of prevention and control efforts. CDC is not a food safety regulatory agency but works closely with the food safety regulatory agencies, in particular with HHS's Food and Drug Administration (FDA) and the Food Safety and Inspection Service within the U.S. Department of Agriculture (USDA). CDC also plays a key role in identifying prevention strategies and building State and local health department epidemiology, laboratory, and envi-

ronmental health capacity to support foodborne disease surveillance and outbreak response. Notably, CDC data are used to help document the effectiveness of regulatory interventions.

In partnership with State health departments, CDC collects surveillance information on foodborne illness. The States collect data about cases of infections that are of public health importance from doctors and clinical laboratories. CDC helps States investigate outbreaks that are large, severe, or unusual. When a new problem emerges, as happened in 1982 when *E. coli* O157 was first recognized as a cause of human illness, CDC conducts practical research to determine the best diagnostic methods and to define the source of the illness.

To initially make a diagnosis, a patient must seek medical attention, the physician must decide to order diagnostic tests, and the laboratory must use the appropriate procedures. Many ill people do not seek medical attention, and of those who do, many are not tested. Therefore, many cases of foodborne illness go undiagnosed and are not reported. For example, CDC estimates that 38 cases of salmonellosis occur for every case that is actually reported to CDC. Some foodborne infections are not identified by routine laboratory procedures and require specialized, experimental, and/or expensive tests that are not generally available. When there is an outbreak of illness and routine testing does not identify the microbe or other causes, samples from the patients may be sent to the State public health laboratory or to CDC for more specialized testing. Less than half of all foodborne outbreaks have known causes or etiology.

Surveillance and Epidemiology

CDC specializes in the critically important public health activities of surveillance, epidemiologic response, and investigation of disease. Routine disease surveillance systems coordinated by CDC, combined with CDC epidemiology offices and laboratories provide an essential early-information network to detect potential threats to the public in the food supply. These systems can be used to indicate new or changing patterns of foodborne illness.

In 1993, there was a large multi-state outbreak of *E. coli* O157 infections in the Western United States. In order to prevent future severe outbreaks by enabling rapid comparison of bacteria isolated from ill persons around the country, an effective surveillance network called PulseNet was developed. PulseNet is the national network for molecular subtyping of foodborne bacteria, which was developed in collaboration with the Association of Public Health Laboratories (APHL) and is coordinated by CDC. The laboratories participating in PulseNet are in State health departments, some local health departments, USDA, and FDA. PulseNet plays a vital role in surveillance for and investigation of foodborne illness outbreaks that were previously difficult to detect. For example, when a clinical laboratory diagnoses *E. coli* O157 is made in a patient, that bacterial strain is sent to the participating PulseNet laboratory where it is subtyped, or "DNA fingerprinted." The "fingerprint" is then compared with other patterns in the State, and uploaded electronically to the national PulseNet database maintained at CDC, where it can be compared with the patterns in other States. This gives us the capability to rapidly detect a cluster of infections with the same pattern that is occurring in multiple States. The PulseNet database, which includes approximately 120,000 DNA patterns, is available to participating laboratories and allows them to rapidly compare patterns. Once a cluster of cases with the same DNA pattern is identified, epidemiologists then interview patients to determine whether cases of illness are linked to the same food source or other exposures they have in common. The strength of this system is its ability to identify patterns even if the affected persons are geographically far apart, which is important given the reality of U.S. food distribution systems. If patients have been exposed to a specific food or to another source of infection and the case count for that illness is larger than one would expect for the time period, the cluster is determined to be an outbreak with a common source.

The group of epidemiologists in the States and at CDC who regularly investigate and report on these outbreaks is called OutbreakNet. The OutbreakNet participants use standardized interview methods and forms and rapidly share the investigation data. With this collaboration, outbreaks can be investigated in a matter of days rather than weeks. As a consequence, CDC can more rapidly alert FDA and USDA about implicated food products associated with foodborne illness so that all three agencies can collaboratively take actions to protect public health. Tracing the implicated food back from consumption through preparation, to distributors, and sometimes back to a field or farm can help determine how the contamination occurred, stop distribution of the contaminated product, and prevent further outbreaks from occurring. OutbreakNet and CDC's overall efforts to continuously improve methods and to train epidemiologists, laboratorians, and environmental health specialists are

making investigations of outbreaks faster and more likely to identify the source. With this enhanced capacity, the public health system can rapidly identify implicated foods with precision and minimize the impact of the outbreak.

Another important surveillance network is CDC's Foodborne Diseases Active Surveillance Network (FoodNet). This network is a collaboration among 10 State health departments, USDA, and FDA that closely monitors the human health burden of foodborne diseases in the United States. It produces reliable estimates of the burden and trends over time for foodborne infections of public health importance. In the participating sites, FoodNet conducts active surveillance for foodborne diseases and also conducts related epidemiologic studies that look at sporadic and outbreak foodborne infections to help public health officials better understand the epidemiology of foodborne diseases in the United States and how to target prevention strategies. We have PulseNet to detect possible outbreaks, OutbreakNet to investigate and report them, and FoodNet to track general trends and define where more effective prevention strategies are needed.

These networks stand prepared to detect a public health event related to the food supply. For example, after investigations of PulseNet-identified clusters of *E. coli* infection focused attention on the need for specific controls during ground beef processing, regulatory and industry practices changed in 2002, and the incidence of *E. coli* O157 infections began to decrease sharply. By 2005, the incidence of *E. coli* O157 infections as measured in FoodNet had dropped 29 percent since the baseline period of 1996–1998, which very nearly met the goal for Healthy People 2010. During the same time period, the occurrence of *Listeria* infections decreased by 32 percent.

In 2000, in collaboration with FDA and eight States (California, Colorado, Connecticut, Georgia, Minnesota, New York, Oregon, and Tennessee), CDC established the Environmental Health Specialists Network (EHS–Net). The purpose of EHS–Net is to assist State health departments in their efforts to improve the practice of environmental health service programs. EHS–Net is a collaborative forum of environmental health specialists (EHSs), epidemiologists, and laboratorians who work to identify and prevent environmental factors contributing to foodborne and waterborne disease outbreaks.

EHS–Net has been instrumental in characterizing policies and practices of retail foodservice establishments associated with foodborne outbreaks. For instance, a recent EHS–Net study found that food safety certification of kitchen managers in restaurants appears to be an important foodborne outbreak prevention measure. The EHS–Net also studies policies and practices of retail foodservice establishments in handling specific foods that have been associated with past foodborne outbreaks. Studies such as these provide regulators with the science-based practical research necessary for adopting recommended practices and for developing new or evaluating existing foodborne disease prevention measures.

CDC Goals

CDC is adapting to meet 21st century health and safety threats. New strategies, innovations, and goals bring new focus to the agency's work, allowing CDC to do even more to protect and improve health. CDC has developed four major overarching goals, all of which specifically involve foodborne illness-related activities: Healthy People in Every Stage of Life, Healthy People in Healthy Places, Healthy People in a Healthy World, and People Prepared for Emerging Health Threats. In addition to the efforts previously described, activities that contribute to these overarching goals include working with physicians and clinical labs to promote proper diagnosis and treatment; educating consumers and promoting safe food practices in homes, restaurants, and institutions; monitoring antimicrobial resistance among microbes that can cause foodborne illness; and enhancing public health networks to detect and respond to outbreaks faster.

CDC'S ROLE IN THE RECENT *E. coli* OUTBREAK RELATED TO SPINACH

On Friday, September 8, 2006, CDC officials were alerted by epidemiologists in Wisconsin of a small cluster of *E. coli* serotype O157:H7 infections of unknown source. Wisconsin also posted the "DNA Fingerprint" pattern of the cluster to PulseNet, thus alerting the entire network. Separately, the State health department of Oregon also noted a very small cluster of infections that day and began interviewing the cases. On September 13, both Wisconsin and Oregon reported to CDC that initial interviews suggested that eating fresh spinach was commonly reported by cases in both clusters of *E. coli* serotype O157:H7 infections in those States. PulseNet showed that the patterns in the two clusters were identical, and other States reported cases with the same PulseNet pattern among ill persons who also

had eaten fresh spinach. CDC notified FDA about the Wisconsin and Oregon cases and the possible link with bagged fresh spinach. CDC and FDA convened a conference call on September 14 to discuss the outbreak with the States.

Quick sharing of information among the States, CDC, and FDA led to FDA warning the public on September 14 not to eat fresh bagged spinach. On September 15, as the number of reported cases approached 100, CDC activated its Director's Emergency Operations Center (DEOC), which provided a facility conducive to an intensive team effort. Working in the DEOC improved coordination for daily inter-agency calls, for numerous calls among FDA, CDC, and the States, and for communication activities.

The epidemiological phase of the *E. coli* O157 outbreak response was composed principally of CDC and State PulseNet and OutbreakNet Team members. Cases were identified by PulseNet and interviewed in detail by members of OutbreakNet. Leftover spinach was cultured at CDC, FDA, and in State public health laboratories. CDC and FDA also collaborated on updated analytical methods and provided reagents to State laboratories. The epidemiologic investigation indicated that the outbreak was associated with bagged spinach produced under multiple labels in a single plant on a single day during a single shift. CDC also worked with teams in Wisconsin, Utah, and New Mexico to conduct a formal case-control study, which was useful in confirming that the risk was associated with one processing plant.

Coordination with FDA was essential for investigating the outbreak. Frequent conference calls relayed the data on spinach purchases and sources to FDA, guiding the ongoing investigation of possible production sites of interest. At FDA's request, an experienced hydrologist from CDC's National Center for Environmental Health was deployed to California to join FDA and the California Food Emergency Response Team in the investigation of possible environmental sources of contamination that led to this outbreak. To ensure that information was disseminated to the public as accurately and quickly as possible about health threats and other information related to this outbreak, CDC and FDA coordinated their communication strategies and messages and discussed these strategies in daily calls with State health officials. CDC utilized its Emergency Communication System, part of its DEOC, to coordinate internal and external communications, such as press releases, teleconferences, and web postings.

CDC also provided information via the Health Alert Network (HAN) Messaging System, disseminating updates directly or indirectly to over 1 million individuals including State and local health officers, public information officers, and others.

CDC's daily posting of case updates ended on October 6 when it was clear that the outbreak was over, although PulseNet continues to monitor the frequency of this pattern among all diagnosed *E. coli* O157 infections. Between August 1 and October 6, a total of 199 persons infected with the outbreak strain of *E. coli* O157:H7 were reported to CDC from 26 States. Among the ill persons, 102 were hospitalized, 31 had hemolytic uremic syndrome which can lead to kidney failure (HUS), and three persons died. Eighty-five percent of patients reported illness onset from August 19 to September 5. Among the 130 patients for which a food consumption history was collected, 123 (95 percent) reported consuming uncooked fresh spinach during the 10 days before illness onset. In addition, *E. coli* O157:H7 with a DNA "fingerprint" pattern matching the outbreak strain was isolated from 11 open packages of fresh spinach that had been partially consumed by patients.

For this investigation, a confirmed case was defined as a culture-confirmed *E. coli* O157:H7 infection in a person residing in the United States, with illness onset from August 1 to October 6 (or, if date of onset was unknown, *E. coli* O157:H7 isolated from August 1 to October 6) and a PulseNet "fingerprint" pattern identified by the XbaI restriction enzyme that matched the pattern of the outbreak strain. August 1 was selected as the earliest illness onset date in the case definition to ensure that the earliest cases in the outbreak were identified and investigated. However, the first six confirmed cases (with illness onsets during August 2–15) were in persons who did not report eating fresh spinach during the week before illness onset. The first person who reported recently eating fresh spinach and had infection with the outbreak strain fell ill on August 19. Thus, August 19 marked the effective beginning of the outbreak.

This outbreak strain of *E. coli* O157:H7 is one of 3,520 different *E. coli* O157:H7 patterns reported to CDC PulseNet since 1996. Infections with this strain have been reported sporadically to CDC's PulseNet since 2003, at an average of 21 cases per year from 2003 to 2005. This finding suggests that this strain has been present in the environment and food supply occasionally, although it had not been associated with a recognized outbreak in the past.

The time from illness onset to confirmation that a case of *E. coli* O157:H7 is part of an outbreak is typically 2–3 weeks, including the time required for an infected

person to seek medical care, for healthcare providers to obtain a diagnostic culture, transfer the bacterial strain to a public health laboratory, perform "DNA fingerprinting," and submit the "fingerprint" pattern into the national PulseNet database at CDC. In this outbreak, the average time from illness onset to DNA pattern submission to the national database at CDC was 15 days.

Parallel laboratory and epidemiologic investigations were crucial in identifying the source of this outbreak. Timely PulseNet "fingerprinting" by State public health laboratories, "fingerprint" pattern submission by States to the PulseNet database at CDC, and analysis of "fingerprint" patterns in the CDC PulseNet national database resulted in rapid detection of the outbreak. Rapid collection of standard case exposure information by OutbreakNet epidemiologists in affected States and sharing of exposure information among States and CDC led to rapid identification of the suspected food source and public health action.

COLLABORATIONS WITH FOOD SAFETY PARTNERS

Council to Improve Foodborne Outbreak Response

The epidemiology of foodborne and diarrheal diseases is always changing, the result of changing diagnostic and subtyping capabilities in laboratories, newly recognized and emerging pathogens, changes in food production, distribution, processing, and consumption patterns, demographic shifts, and many other factors. To successfully manage foodborne outbreak challenges, public health agencies must constantly adapt. The Council to Improve Foodborne Outbreak Response (CIFOR) was created to help develop model programs and processes that will facilitate the investigation and control of foodborne disease outbreaks. CIFOR's agenda includes improving the performance and coordination of relevant local, State, and Federal public health agencies involved in epidemiology, environmental health, laboratory sciences, and regulatory affairs. CIFOR, co-chaired by the Council of State and Territorial Epidemiologists (CSTE) and the National Association of County and City Health Officials (NACCHO), will develop multi-state outbreak guidelines, a repository for resources and tools, and performance measures for response to enteric illness. CIFOR includes representatives from CDC, FDA, USDA, CSTE, NACCHO, APHL, the Association of State and Territorial Health Officials, National Environmental Health Association, and the Association of Food and Drug Officials.

Council of Association Presidents

Integrating the food safety and food defense efforts of Federal, State, and local public health, veterinary and food safety officials is of critical importance. CDC is collaborating with FDA, USDA, and the Council of Association Presidents to raise awareness of current and emerging issues and to promote coordination. The Council comprises the 10 leading public health, veterinary, and food safety associations that work the spectrum of food safety and food defense, from animal feed to human health. The collective expertise and collaboration of these associations are essential to develop and implement integrated efforts, provide needed training, and build the multidisciplinary capacity necessary to address food-related emergencies.

CONCLUSION

The recent outbreak of *E. coli* O157 infections related to spinach was large and deadly. Although the overall number of infections caused by this organism has decreased in recent years as the safety of meat has improved, this outbreak illustrates that better control and prevention measures are needed in other sectors of the food industry before we can consider *E. coli* O157 under adequate control. Although spinach has not been a source of *E. coli* O157 outbreaks before, lettuce has been implicated on several occasions. In fact, there have been 20 outbreaks involving leafy greens, 7 of which were traced to California. A better understanding is needed of the mechanisms by which leafy greens become contaminated so contamination can be interrupted.

The event illustrates how a large and widespread outbreak can occur, appearing first as small clusters, and then rapidly increasing if a popular commercial product is contaminated. It also illustrates the importance of existing public health networks: the laboratories performing PulseNet "fingerprinting"; the epidemiologists interviewing patients and healthy people and collecting leftover spinach; the multidisciplinary approach to the investigation; and the close communication and collaboration among local, State, and Federal officials. This investigation illustrates what a robust public health system can do and lays down a benchmark for the future. Without question, a rapid and accurate analysis of and response to an outbreak will result in prevention of exposure to contaminated products and will stop further illness and death.

Produce-related outbreaks are a growing challenge to public health. As this and other outbreaks indicate, research should focus on tracing the specific pathways that connect fields of leafy green vegetables with potential animal reservoirs of *E. coli* and other disease-causing microbes. CDC is prepared to continue working with regulatory authorities, food and environmental microbiologist scientists, and the food industry to find long-term solutions to this challenging problem.

The CHAIRMAN. Thank you very much. We do appreciate your being here today. We appreciate the information that you shared. We, in the United States, take a lot of things for granted and one of those is our fresh produce. I know from going to other countries that most of the time, you're briefed and told, don't eat any vegetables and a lot of that has to do with the water, which is another thing we're fortunate on here in the United States. You can drink the water here.

But we want it to be safer yet. We want to find the best ways to handle all of this, the best ways to get coordination, the best ways to make sure that our system works and people are as secure as possible.

Dr. Brackett, has the FDA discovered any previously unknown weaknesses in the food safety system as a result of this event? Are there lessons from this incident that can be used to improve FDA's ability to respond to an intentional contamination of the food supply as opposed to an accidental one?

Dr. BRACKETT. Well, thank you, Chairman Enzi. We've probably learned more from this particular outbreak than we had learned from all the previous outbreaks combined and there are many different lessons learned that we'll accumulate from this. The investigation is still ongoing and once it's done, we hope to catalog those lessons learned and use those in the future.

But to your last point, as far as intentional, I have to say that we believe that the response that happened once we learned what the illness was caused from, was about as fast and as efficient as we could have possibly hoped. We were able to communicate very well with CDC as well as with the States and actually with USDA as well, to try to first of all isolate the product in the minds of consumers so that they could avoid that. Second, also initiate the investigation immediately so that we could find out what the cause was.

The CHAIRMAN. Thank you. Dr. King, you indicated in your testimony that data from the outbreak was posted to PulseNet on September 8 but Dr. Reilly states that California didn't know about the outbreak until nearly a week later, on September 14 when it was announced publicly. Can you explain what happened? What is the discrepancy or what was going on?

Dr. KING. I'm not quite sure of the discrepancy. I know on September 8, the Wisconsin Public Health Laboratory posted a PulseNet web-board messaging to all the States about this *E. coli* outbreak and about the matches that they say in the DNA fingerprinting. So that was available. It was later sent to CDC, to our national database. It was September 11 when CDC actually confirmed that. So the information was available from the State on September 8. It came to us, we did the confirmation on September 11.

The CHAIRMAN. OK. Dr. Brackett again, some people use the outbreaks as evidence that the Food and Drug Administration needs

mandatory recall authority. Has a company ever not agreed to voluntarily recall a product associated with an outbreak when asked by the FDA?

Dr. BRACKETT. Not to my knowledge, that has not happened. Sometimes there have been a few cases where they may have balked but they've always done the right thing, which is to recall the product. In this particular case, the company, once they were notified, immediately recalled their product.

The CHAIRMAN. Thank you. Back to you again, Dr. King. The CDC conducts a lot of pathogen testing and surveillance of foodborne illnesses. What are the gaps in the ability to do the sort of testing and surveillance that need to be filled to protect consumers and is there a way that we can shorten the timeframe?

Dr. KING. Yes, it's the same as some of the lessons learned that Dr. Brackett talked about. I think first of all, we understand that prevention is better than tracing these outbreaks after the event has happened. Compression time is really important because a few days can make a big difference in terms of potential contamination of people. So we have continued to look at ways of how to compress time.

There is a built-in timeframe that's necessary to report these. When a person eats some food that is contaminated, until he or she actually has signs of that disease—if he or she goes to a physician, if samples are taken, if cultures are then grown, if those cultures from clinical laboratories then have to be transported to the State public health laboratory to do the PulseNet and then transferred to CDC.

In this case, it was 15 days between a case of illness and actually PulseNet confirmation at CDC. We think there are ways to probably compress that time. Quicker movement through the system in terms of moving cultures from commercial labs to the State lab, for State labs to actually put this up for us to identify can save a few days.

But also, investigating this time and our working and looking at a brand, new diagnostic technology and that is, to move from PulseNet the DNA fingerprinting, if you will, to more looking at the genome of the microbe. That will actually compress time, make it faster, make it more accurate, make it more amenable to working with large databases because you're actually looking at the genome and amino acid strains.

We believe that this will increase the amount of time, or decrease the amount of time, if you will, and also give us actually more accurate diagnosis. So we are actually working on that and that will probably be the next generation of diagnostics.

The CHAIRMAN. Can you give me a little indication of how long it takes to grow a culture and also to do the DNA testing?

Dr. KING. Sure. I'm just going to give you some idea. In this case, from when a person was infected or ate the contaminated spinach in this case, it was about a 48-hour timeframe for that incubation period. That patient then goes in to a physician's office or a healthcare worker's office and is identified. In this case, because it is *E. coli*, there are very serious clinical cases with often hemorrhagic diarrheas and this particular strain was a pretty virulent strain.

There is the time of treatment. Usually stool samples are taken and there is anywhere from 1 to 5 days for that to happen. The cultures are grown from 1 to 3 days. Once the *E. coli* had been identified, there is also a shipping time that goes from a clinical laboratory, which are often private labs, to the State lab and that can be anywhere from almost immediate to a week. Then anywhere from 1 to 4 days to get to CDC. So you can see where some of the compression could take place.

The CHAIRMAN. Thank you. I'll now turn it over for questioning to our expert in this area, Senator Burr.

Senator BURR. Thank you, Mr. Chairman. Doctors, welcome. Let me go back through some of the dates if I can. I'm having a tough time putting these things together. In the written testimony, Dr. King, I think you said CDC officials first heard about the *E. coli* outbreak by epidemiologists from Wisconsin on Friday, September 8. Is that correct?

Dr. KING. On—I'm just making sure I can give you the accurate information. On September 8—we actually knew it on September 7—the Wisconsin laboratories were isolating these from stool samples. Wisconsin actually put up then, the laboratory posting at the PulseNet Website on September 8.

Senator BURR. So on the PulseNet Website, they put up and that was—that coincided with when CDC understood there was an outbreak?

Dr. KING. We knew then that Wisconsin had matching isolates.

Senator BURR. OK. And it was September 8, September 9, September 10, September 11 before it was confirmed that this was, in fact, the case?

Dr. KING. Well, I think—you know, the key to us was that we confirmed that on September 11 and we also identified that same match. So we confirmed what Wisconsin knew.

Senator BURR. Walk me through what took place from the 8th to the confirmation on the 11th?

Dr. KING. Let me get the right answer.

Senator BURR. Sure, sure.

Dr. KING. We had a call from Wisconsin that night, on Friday and that data then was sent to us—and I'm not sure if it was sent Friday night or over the weekend but we did confirm it on the 11th.

Senator BURR. Mr. Chairman, I'm not sure what is going on with our mic system but I'll try to go ahead. Help me understand something. CDC is notified of an *E. coli* outbreak. How long does it take for you to confirm that, from the time that you hear it to the time that you confirm it? Is it 4 days? Is it 2 days? Is it 1 day?

Dr. KING. Well, it depends when the State actually uploads and sends that to us for computer analysis.

Senator BURR. OK. Did the State upload it on the 8th? Did you receive it on the 8th and then confirm it on the 11th? Is that correct?

Dr. KING. That's correct.

Senator BURR. Does it take the 9th, the 10th and the 11th to do this confirmation or was there a period of time where there was not the degree of attention to confirming this?

Dr. KING. Let me kind of explain.

Senator BURR. Sure.

Dr. KING. You know, the thing for us that really made this an outbreak was September 13. The real—and that happened because another State actually had an outbreak. In this case, it was Oregon.

Senator BURR. Well, the 13th also. Wisconsin now has done their interviews. They've now determined that they think spinach is the culprit, correct?

Dr. KING. They have a high probability that they think that may be the case, yes.

Senator BURR. You state in your testimony that it was a small cluster. So there were not many people to interview. I'm trying to understand when Wisconsin says we've got an *E. coli* outbreak and yes we have all of these guidelines for growers and processors and we have guidelines at CDC and FDA as to when this happens, here's what we do. Were those guidelines followed internally? Did we process the information that we were supplied as quickly as we could or did we not take this as seriously as it ended up being?

Dr. KING. I think we took it seriously. Also to let you know about what's happening in the background as this goes on, every day we get confirmed cases of *E. coli*. Every day we get confirmed cases of salmonella. As a matter of fact, you know, there's some estimates right now that there may be as many as 73,000 *E. coli* cases every year. So the idea of having eight cases in a single State is something certainly of interest and because it was matched, there was interest. We also are continuing to look at "background noise." Cases that come in, other *E. coli* cases that are positive that we also need to check. It's when that came to us, second State, with far geographic differences that that really rang the bell for us that this was an outbreak that probably wasn't a source from one single State.

Senator BURR. Does every State have PulseNet?

Dr. KING. Yes, sir. Every State does and some States actually have more, like California and some cities actually have their own PulseNet system, like New York.

Senator BURR. When PulseNet found a match between the samples of DNA fingerprints from Wisconsin and Oregon, who was notified?

Dr. KING. There is actually a PulseNet Board that goes up, where those results then are available to all members of that system. So frankly, every State then, should have understood that there was a match and when that happened, we also have a system called Outbreak Net, where we actually then put together epidemiologists, State public health officials and actually talk about this.

Senator BURR. How are they notified?

Dr. KING. That is either through conference call or through the Internet process.

Senator BURR. So in every State, they either have an Internet communication from the CDC or they got a phone call.

Dr. KING. That's correct.

Senator BURR. OK. Does PulseNet recognize a match or does a human recognize a match?

Dr. KING. Say that again, Senator.

Senator BURR. Does PulseNet recognize a match or does a human recognize a match?

Dr. KING. Actually, it's first recognized by a pretty complex computer system. We go back then and check it by individuals just to make sure. But the initial matching is actually done through the computer system itself.

Senator BURR. In the days after 9/11, I was in the House and as we began to work—I think, Mr. Chairman, on the first bioterrorism bill, I was amazed at that time to find out that every public health entity in America did not have a fax machine. Yet at the time, our communications—standard communication from government to those entities was by fax. In those cases, if somebody didn't recognize the fact that there was a public health entity in the network that needed a phone call versus a fax, they were never notified.

Now, you've already told me that every State has PulseNet so they should have access.

Dr. KING. These are the public health labs that we have as part of the network. There would be other public health labs around States that may not—that aren't our PulseNet network.

Senator BURR. On a State level, who would have access to PulseNet? People in local health departments or just people within the State administration?

Dr. KING. All the PulseNet users, epidemiologists and people in the State diagnostic laboratory.

Senator BURR. So, in essence, they could get the information but it may never get to the local public health infrastructure of an affected area, through PulseNet. Am I correct?

Dr. KING. I don't believe it really has to. Once the information gets out and it's publicized and the public knows, then I think that we've done what we need to do. So not every laboratory in the United States would need to have PulseNet.

Senator BURR. Well again, I'm trying to understand the process and then put it in reverse and try to understand if a local person doesn't have access to PulseNet, then what compels a local public health entity to make the right notifications to State officials that an outbreak may have started. We've got a system that is connected between two points. Unfortunately, there seems to be a missing point out there on the receiving end, on the transmission end, that has to be initiated by either a hand-off to somebody on your part or an initiation at a local level by somebody to the State. If, in fact, you have a breakdown either place, then you've got potential delays, which is a health issue. If other States had submitted samples with identical DNA fingerprints, how would the CDC have notified those States that the fingerprints matched what they found in Wisconsin and in Oregon?

Dr. KING. Senator, that did happen.

Senator BURR. Is that done automatically by PulseNet?

Dr. KING. It's done either through a phone call or an email or both.

Senator BURR. But it requires a human intervention to initiate that, is that correct?

Dr. KING. That's correct.

Senator BURR. In your written testimony, you stated that in this outbreak, the average time from illness to onset to DNA pattern submission to the national database at CDC was 15 days.

Dr. KING. Correct.

Senator BURR. Two weeks seems like a long time to me. Is that standard or is this the exception to what you would hope that timeframe to be?

Dr. KING. We actually saw this as how the system worked pretty well. I thought this was a success in terms of the speed that that got done. Could we shave off a few more days? We always are looking to do that. But 15 days to identify a 157, do the matches, understand it's in multiple States, get the information out, FDA's rapid response, to understand that spinach was involved. You generally have to go through, often a complicated case control study to understand.

Senator BURR. Well, isn't that the Wisconsin interviews, though?

Dr. KING. It was the interviews but it was suspicious that it was spinach. Oregon—it was also possible that there was other foods that were possible. So they weren't 100 percent sure. When we got the call from Oregon, Oregon said, we think this may have very well involved spinach. So that's when it really started to come together.

Senator BURR. According to the Association of State and Territory Health Officers, 42 percent of the current epidemiology workforce lacks formal academic training in epidemiology. That's a little worrisome to me. If you believe that's an accurate percentage, tell me how we fix that.

Dr. KING. I've heard that statistic as well. It's not good news. My understanding is that of the jobs that are defined as epidemiology jobs, I think 42 percent of the people don't have formal training in epidemiology. So is there a cross over—I don't know. I think that's unacceptable, Senator, and I think it means that we have a lot more work to do, to do further training and build up, if you will, the capacity of an infectious disease workforce. I think it is really important and I would agree with your assessment.

Senator BURR. Thank you, Dr. King. I haven't meant to pick on you but I wanted to make sure in this first round of questions, that I was able to understand these timeframes a little bit better. If I understand the Chairman's intent, it is to bring up the second witness and then bring these two doctors back up to the table. Am I correct?

The CHAIRMAN. Yes, I hope they would stay. I need them to stay for the next testimony because that may bring up some more questions.

Senator BURR. I have some additional questions but I'll save them for that period, if it's okay with the Chairman.

The CHAIRMAN. OK. I've got a couple that came up as a result of your questions that I want to ask. When you're talking about shipments from the testing labs to the State or to the Federal labs, what gets shipped? Is it samples or is it data?

Dr. KING. In this case, it is samples. So it's collected from a healthcare worker. It is moved then to usually a clinical laboratory, which is generally private. So there is a period of time when that happens. It takes several days, actually, for that culture to grow.

When it is identified as *E. coli*, the sample of the bacteria, is moved into the PulseNet State laboratory and that's where the procedure takes place for it to be segmented and worked on, enzymes, restriction enzymes and actually go then to the Pulse shell part of that.

The CHAIRMAN. Now you've mentioned the eight people in Wisconsin. Does this process speed up if it's a larger sample of people? Or does it still take the same amount of time?

Dr. KING. It still takes a finite period of time to grow the sample, to ship it, etcetera. I think what we do know is that once the information got out that there were matches and other States understood that an outbreak may be pending or starting, then I think people were much more observant. We had calls with clinicians that talked about sending samples and treating cases, etcetera. So once that got known, I think people were more aware and more alert. But it does take a finite period of time to go through those steps.

The CHAIRMAN. So you're saying that if there is an intentional contamination, we're still looking at 15 days?

Dr. KING. That's what it was in this case and you have to remember that also included the probable confirmation that spinach was the vehicle. It usually takes a little while longer to really go through what we call case control studies, talking to people that became ill, going back and seeing what they ate at certain times and comparing those with people that weren't ill and do that kind of a comparison to get a statistical analysis of what the vehicle was.

The Chairman: This is a question for both of you. Once you find something, how else, besides PulseNet, do the FDA and/or the CDC reach out? Do you use other ways, such as the Health Alert Network? What other mechanisms are there? A question for both of you.

Dr. BRACKETT. Well, we'll use any kind of mechanism that we can, one of which is, of course, through press releases, if it's a general piece of knowledge. We will use the networks that are established with the public health system, in some cases, with the agriculture departments, if they have responsibilities for foods, to alert them that there might be something going on as well. So it's a variety of different ways. There is a network of individuals who know each other within the States and within the Federal Government that will contact each other.

The CHAIRMAN. Thank you. Dr. King, did you have some additional comments on that?

Dr. KING. Yes, sir. We also use, as I mentioned, a method called Outbreak Net, where we actually then incorporate epidemiologists and key State health officials in all the States, to talk about the outbreak, to get different ideas, to make sure that they are aware. We use conference calls a lot. During that outbreak, we had conference calls almost daily with States and diagnostic laboratories. Then they really have a network of networks in terms of what they do within their own States.

The CHAIRMAN. Thank you. Yes?

Senator BURR. Could I ask two additional questions?

The CHAIRMAN. Sure.

Senator BURR. Is spinach safe to eat today?

Dr. BRACKETT. The comment that we've made is that it is as safe as it was before the outbreak, which is to say, the relative risk is low considering the total amount of tonnages, the number of servings that are eaten for a year. However, does that mean that improvements can't be made? No. I think that we can make improvements to the safety of all of our ready-to-eat produce so that's our goal. But I would say that what we—we will more likely let consumers know when we know something is not safe and until that time, they are to assume that there is no reason not to eat it.

Senator BURR. Is the contamination, the *E. coli* contamination that took place with the spinach, was it a surface contamination or was it absorbed through the root system of the spinach?

Dr. BRACKETT. Well, both are possibilities. We really don't know, is the answer. Yet hopefully at some point, we'll find out. But it's more than likely that it was surface contamination, just by the environmental possibility and the number of people that became ill. But there is at least some scientific evidence to say that organisms like that can be uptaken through the roots in plants or through the flowers. But we have no evidence that that was the case in this particular instance.

Senator BURR. I thank you, Mr. Chairman.

The CHAIRMAN. Thank you very much and I thank you, Dr. Brackett and Dr. King and would ask that you have a seat until we finish the next testimony and we'll see if there are additional questions that come out of that. While you're doing that though, I would mention that this is only a week after the report that those people who eat 2.9 servings of vegetables a day live 5 years longer than those who only eat one serving a day. So the green vegetables are particularly important.

We'll now hear from Dr. Kevin Reilly, who is the Deputy Director of Prevention Services of the California Department of Health Services. Dr. Reilly will discuss the role of this department in identifying and containing the *E. coli* outbreak. We thank you for being here, Dr. Reilly, and for your testimony.

STATEMENT OF DR. KEVIN REILLY, DEPUTY DIRECTOR, PREVENTION SERVICES, CALIFORNIA DEPARTMENT OF HEALTH SERVICES, SACRAMENTO, CA

Dr. REILLY. Good afternoon, Chairman Enzi and Senator Burr. I am Dr. Kevin Reilly. I work with the California Department of Health Services. Our programs played an important partnership in the investigation of this *E. coli* O157:H7 outbreak, the multi-state outbreak resulting in more than 200 illnesses, 3 fatalities in 26 States and serious economic impacts, both on the public sector as well as within the industry, in California where this spinach came from.

Thank you for having me here today to discuss our role in the investigation and our recommendations to help prevent such an outbreak due to contaminated fresh produce from happening again in the future.

As was mentioned earlier, California first learned of the outbreak during a nationwide teleconference on the 14th of September. By

the end of that teleconference, Federal officials and the affected States had reported 51 cases of a O157:H7 and one possible fatality in 13 States.

They were related based on the bacterial genetic testing that Dr. King mentioned fairly extensively. By the end of that week, there were over 100 cases reported in 21 States. What happened in the very beginning was that a significant suspected risk factor came up in that very first teleconference—consumption of fresh, pre-packaged spinach by the individuals who had become ill.

I won't mention or repeat Dr. King's testimony. I did talk a little bit about genetic testing but this played a key role in this outbreak. In the past, public health officials have not really had good ways of looking at—trying to link seemingly unrelated cases that may represent a widespread outbreak with very low rates of infection. That changed in 1993 with a very large outbreak of *E. coli* O157:H7 in the western United States, associated with Ground B, if you may remember this outbreak. CDC did an excellent job of developing the PulseNet system at that point by developing enzymes and methodologies, standard methods for Pulse-filled gel electrophoresis, genetic is done and really has created an excellent tool for us to use in these outbreaks.

As Dr. Brackett noted, on September 14, the FDA District Office and the Department of Health Services in California conducted a conference with three major fresh produce facilities, processors, in the Salinas Valley. These are entities whose products had been named by patients as part of this outbreak investigation. We advised those firms in that teleconference of the outbreaks and made very strong recommendations that they initiate voluntary recalls of the product at that point, based on the information available.

On that first day, I believe 22 of 39 patients who had been interviewed, recalled consuming fresh pre-packaged spinach in the several days prior to the onset of illness. That's at a rate much higher than the regular consumption rate of spinach by the general population based on data published by USDA on a regular basis.

The majority of these patients had consumed products that were manufactured, processed or co-processed by a particular company in San Juan Batista, California called Natural Selections Foods. We informed them of the circumstances. We told them that FDA and DHS would be onsite in their facility later that day and we started the investigation at that point.

Natural Selections confirmed that they co-package for several large manufacturers, national brands—Dole, Trader Joe's and several private companies that had been named by the patients. Later that day—actually the next day, Natural Selections did a voluntary recall of their product.

FDA and DHS initially activated our CalFERT Team. That's our California Food Emergency Response Team. This is a specially trained group of microbiologists, food investigators, epidemiologists and other persons with real expertise in farm investigation and produce trace-backs. In the past, DHS and FDA have done their own thing. They've done independent investigations, sometimes with better coordination than others, but clearly that results in duplication, inconsistency and basically confusion, not only for ourselves but for the industries that we were investigating.

DHS and FDA, about a year ago, sought to fix that. That's when we put together this team of Federal and State employees to be able to do these investigations onsite and minimize those sorts of problems. We communicated very well, trained well together and investigated well together.

Over the following week, information about the epidemiologic investigation that was ongoing around the country, including the isolation of spinach—of the *E. coli* O157:H7 strain type, the outbreak strain, from spinach packages consumed by some of the patients that had been affected and as well as work with the Natural Selections processing plant resulted in nine farms being identified. This is within a week's time of our first knowledge of the outbreak. That's unprecedented. We've never been anywhere near that fast in doing a trace-back to determine location and source of an outbreak, a vehicle, food vehicle in an outbreak.

The CalFERT team members were onsite immediately. As the investigation matured, we started to find that the product in question was produced on a single day, August 15. It was a single processing plant. It was a single shift on that processing plant. Based on a very thorough record review, we were able to narrow the number of farms implicated down to four and this was in two California counties in the Salinas Valley, San Benito and Monterrey County.

We went on those farms immediately, within 2 weeks of the initial outbreak. We discovered that there was no produce on two of the fields that were implicated. The other two had some fresh spinach and other product onsite. Voluntarily, the farmers immediately tilled that under to prevent that from getting into the market. Those fields have not been used in the interim to produce fresh produce. Those potential risk factors have been removed from potential sources for contaminated spinach.

Trace-back investigations are a lot like detective work. We're trying to solve a mystery, trying to figure out the who, where, why, what and when of contamination of fresh produce that may have caused illness. The environmental investigation seeks to identify a long-neck chain—the introduction, survival and opportunity for growth of contamination in the involved foods. In this case, through growing, through harvesting, packaging and ultimately processing of the spinach.

Unfortunately, these sorts of investigations rarely find a definitive cause, a so-called smoking gun, for the outbreak. The environmental investigations are very time consuming. Many times it will take several months to complete these. It involves dozens and dozens of site visits to a number of different locations and collection of a large number of specimens. We sometimes use an analogy of trying to—imagine trying to do an investigation of a multi-car auto accident but you don't get to start that investigation until a month after the accident occurs. That's very much the way it works with our investigations in that by the time patients have been diagnosed, reported to local public health, to State public health and the investigation, epidemiological laboratory investigations are concluded, that could be several weeks, at best. So we have a real hard task before us in trying to go back to the location and find out what happened on that day.

Our environmental investigations are very standardized. We have staff with specific assignments. We do very in-depth farm management and employee interviews. We systematically review the environment and practices on those fields. We carefully document all these findings and conduct extensive environmental sampling for bacteriological testing.

On all four of these implicated farms, the teams reviewed the farms' surroundings, the irrigation sources, wildlife, domestic animals onsite, farm worker hygiene, and collected a lot of samples. Domestic livestock were involved in three of these locations, onsite. You heard testimony about CDC's hydrology expert providing excellent support and looking at irrigation water, well water, water use on the properties. USDA wildlife services helped us with the wildlife issues that we'll get to in just a moment.

The O157:H7 was identified in fecal or water samples at or near all four of these locations. All four of these fields had *E. coli* O157:H7 associated with them. Only one of them, however, had the matched strain, the strain type based on the genetic testing. To date, 10 different isolates from the environment have shown up with that same genetic testing. They come from cattle feces, wild boar feces, water specimens and wild boar that were killed onsite.

Even before we found these isolates, this particular field had a lot of concerns for us. It's in a bowl, in a valley. It's right up against a streambed. It's surrounded by hills that have lots of livestock operation and there are lots of wildlife in this area. The investigators saw very extensive wild pig populations and lots of damage to—the attempts of trying to secure those fields. Fences were knocked down. They were burrowed under. There were tracks through the fields. There were rooting areas—pigs like to root and they had done a very good job on these fields, of rooting onsite. Again, we saw these a good month's time after the harvest dates but it looked very consistent in what could have happened on the day of the contamination onsite.

We saw that there was a real large number of pigs there. Some areas looked like they were pig highways, just that they were running back and forth very regularly and basically spending a lot of time onsite.

When I'm on the highway, sometimes I will get the munchies and stop for a snack. That's what these pigs were doing. They would knock down fences, get under the fences, come off their highways and eat the spinach onsite. I think we have good evidence that these pigs had very regular access to these fields.

One last thing—*E. coli* O157:H7 seems to be very common in the Salinas Valley environment. In the past 2 years, we have worked with USDA to do environmental sampling of the watershed there. We have found periodic contamination on a very regular basis in waterways throughout the Salinas Valley. This looks like a systematic contamination of this environment. We don't know why and we don't know the ecology of all that but it appears that this may play a significant role linking back to the number of outbreaks of O157:H7 that have traced back to the Salinas Valley.

We've heard about some significant issues with this outbreak. It was unusual in that it was very widespread. It was unusually virulent. Half the persons were hospitalized that were infected and

identified. It had a very high rate of kidney failure—HUS in patients that were either very young or very old that were infected.

The other aspect of it that was unusual is this outbreak was investigated very rapidly and within 2 weeks, we were on the farm that was implicated, that was the source likely of this outbreak. That's unprecedented. We have never experienced anything like that in past investigations.

Past investigations—FDA has documented 20 *E. coli* O157:H7 outbreaks in the past 11 years that are linked back to fresh spinach, lettuce or other leafy greens. That's 20 in 11 years. Not all those have had trace-backs but half of them, approximately, that were traced back or half of the total, nine, traced back to the Salinas Valley. Something unusual is going on in the Salinas Valley that has resulted in a number of these outbreaks. Twenty over eleven years is way too many. So you may ask yourself, what have we done about that?

Starting back in 1996, we started working with the industry to come up with good agricultural practices. Some of that document was used in 1998, a manuscript that the FDA put together, which was a recommendation, "A Guide to Minimizing Microbial Food Safety Hazards For Fruits and Vegetables." That was the first time that the idea of good agricultural practices was actively entertained as a good means to try to prevent these sorts of contaminations from happening. That document also talked about good manufacturing practices, things that we're quite used to in the food processing industry.

Following the outbreak in 2002, we started meeting with this industry. We met with the lettuce and fresh green produce industry for about 3 years. We pushed on a research plan. We pushed on the idea of trying to get some funding in to understand what was happening in this environment. But that wasn't enough. We still have outbreaks in that timeframe, all the way to the recent.

CDHS has worked with industry and USFDA to put together a safe processing fresh-cut produce videotape to help train processors and persons on the farm. We've worked with the Western Institute of Food Safety to try to—at UC Davis, to try to look at a research agenda, to try to answer some of these questions and our State health officer has sent a letter to the institute really coaxing and prompting and recommending that the industry step up and take ownership of this problem, to try to help us determine a cause and a solution.

Still not good enough. Some of our best efforts have been to work with the industry. In April 2006, the industry put forward a guideline to lettuce and green leafy commodities, a specific guideline to lettuce and green leafy food safety. This is a good document. It's something that is looking at trying to implement good agricultural practices. The problem is, it's not specific. It doesn't have metrics. It's not measurable and a farmer in a field doesn't know what to do to specifically address some of the food safety risks that are on those fields.

In mid-2006, FDA and DHS started visiting farms in Salinas Valley to try to determine, were these GAPs being applied? And were they being effective? The unfortunate thing is, we had to stop that short because of the outbreak and we had to spend our time

investigating it. But of the sites we visited, we found that a number of them had not begun implementing GAPs and unfortunately, a number of them also were not even aware of what GAPs were. That was concerning to us.

I have a bumper sticker in my office that read, "*E. coli* happens." But I know it just doesn't happen. More importantly, we know how to prevent it. When we are investigating an outbreak that is traced back to the farm, we know where *E. coli* O157 comes from. It's a normal bacteria in livestock and other ruminants. It's a normal bacteria that can be found in wildlife and we know the ways by which it gets onto the fields: through water, fertilizer, manure, farm worker hygiene problems, wildlife, and domestic animals.

Our job is to try to determine which one of those failed or which one of them was responsible for contamination. In this particular outbreak, three of those risk factors came up positive in our culturing, in our microbiology. That's much better than we've done in the past. What it told us is that what we're recommending in good agricultural practices are the way it will work—are going to be effective means of preventing contamination. Three of the areas we have major recommendations from GAPs in the areas we found positive cultures.

We may never be able to actually find exactly what happened on the day that the product was harvested, whether it was the pigs, whether it was the livestock, whether it was an individual traipsing through those fields carrying the bacteria onto the fields, but what we do know is we have tools to help prevent it. That's what we're moving right now, to implement good agricultural practices with this industry in California to reduce that risk.

JPs are of critical importance because as we've witnessed, the ability to prevent contamination in the processing plant doesn't work. We've had a number of outbreaks where the good practices, manufacturing practices in the processing plant have simply not worked, notwithstanding the very high levels of chlorine and really, state-of-the-art practices that have been going on there.

I think our greatest needs are research to try to figure out some of those ecological, microbiological issues and consistent application of these good agricultural practices every day on every farm so that the opportunity for contamination in the fresh produce you and I really want to eat, doesn't happen.

The last issue—we in public health need to balance the absolute need for good nutrition, cancer prevention, cardiovascular disease prevention, and health promotion, that fresh fruits and vegetables provide us. We need to balance that with a risk, though be it a very low risk, of foodborne illness that may unfortunately cause severe illness and even kill you if you are very young or very old or predisposed with immune compromise. That's a difficult situation to be in. But what we are committed to doing is working with the fresh produce industry in California to identify what happens in these outbreaks, to implement stages and steps to prevent that from happening and to provide good consumer confidence that fresh produce consumption not only is good for you but won't put you at risk for foodborne illness.

Thank you for your time. I'm available for questions.

[The prepared statement of Dr. Reilly follows:]

PREPARED STATEMENT OF KEVIN REILLY, D.V.M., M.P.V.M.

Good afternoon Chairman Enzi, Senator Kennedy, and committee members. I am Dr. Kevin Reilly. I am the Deputy Director of Prevention Services for the California Department of Health Services, which in partnership with the FDA, investigated the processing plant and farm sources of spinach implicated in the recent multistate *Escherichia coli* (*E. coli*) O157:H7 outbreak that resulted in 204 persons reported ill and 3 deaths. Thank you for asking me here today to discuss that investigation and our recommendations to help prevent such an outbreak due to contaminated ready-to-eat produce from happening again.

California first learned of the outbreak during a national teleconference on September 14, 2006 where CDC, FDA and a number of States participated. At the beginning of the teleconference, the Federal agencies reported 39 *E. coli* O157:H7 cases and one possible fatality in 12 States that matched on bacterial genetic testing. By the end of the call, the number had risen to 51 cases in 13 States with many more suspected cases being tested. By the end of that weekend, well over 100 patients infected with the outbreak strain had been reported from 21 States.

Prior to 1993, public health agencies did not have an objective way to link seemingly unrelated cases of illness in different States. In 1993, a large outbreak of foodborne illness caused by *E. coli* O157:H7 occurred in the western United States. In this outbreak, scientists at CDC performed DNA "fingerprinting" of the bacterium using a method called pulsed-field gel electrophoresis (PFGE) and determined that the strain of *E. coli* O157:H7 found in patients had the same PFGE pattern as the strain found in hamburger patties served at a large chain of regional fast food restaurants. Prompt recognition of this outbreak and its cause may have prevented an estimated 800 illnesses. As a result, CDC developed standardized PFGE methods and in collaboration with the Association of Public Health Laboratories, created PulseNet so that scientists at public health laboratories throughout the country could rapidly compare the PFGE patterns of bacteria isolated from ill persons and determine whether they are similar. PulseNet has significantly enhanced the ability of public health agencies and laboratories to communicate and more quickly identify "clusters" or foodborne outbreaks. As Dr. King with CDC described, PulseNet played a key role in the early detection of this latest spinach associated outbreak of *E. coli* O157:H7.

In California and many other States, local public health and environmental health agencies have the primary responsibility for investigating foodborne illnesses and outbreaks within their jurisdiction. In outbreaks involving multiple jurisdictions, the State health department takes a leadership role in coordinating the investigation. In other States, the responsibility for all outbreak investigation is at the State health department level. The California Department of Health Services' (CDHS) authority to investigate foodborne illness extends to all levels of food production and distribution—including to the farm level. Under that authority, CDHS partnered with FDA in leading the traceback and environmental investigation to determine the ultimate source of contamination that caused this outbreak.

Following the national teleconference on September 14, the FDA San Francisco district office and the CDHS Food and Drug Branch hosted a conference call with three major fresh pre-packaged spinach producers in the Salinas Valley whose products were identified by patients in the outbreak investigation. CDHS and FDA advised the firms of the outbreak and strongly suggested that the firms consider initiating a voluntary recall of spinach products. As discussed during the national teleconference, 22 of 39 patients reviewed during the call reported consuming pre-packaged fresh spinach in the days prior to onset of illness. The majority of patients that reported specific brands of fresh pre-packaged spinach identified a brand manufactured by Natural Selections Foods LLC in San Juan Batista, California. Natural Selections Foods LLC was informed that an onsite investigation of their processing facility would be initiated that day, and that CDHS and FDA would be requesting distribution information for bagged spinach. Natural Selection confirmed that they pack for Dole, Trader Joe's and other private labels. Natural Selection e-mailed FDA and CDHS a retail distribution data file for product shipped from 8/1/06 to 9/14/06. The following day, Natural Selections Foods announced a voluntary recall of their pre-packaged spinach products.

The FDA San Francisco district and CDHS Food and Drug Branch activated the California-Food Emergency Response Team (CalFERT), a specially trained and exercised group of microbiologists, field investigators, epidemiologists, and others with special expertise in farm investigations and produce tracebacks. In the past, FDA and CDHS investigators would conduct parallel but separate investigations, often resulting in duplication of effort, lack of standardized investigative processes and procedures, and confusion for regulated firms. CalFERT members receive advanced

training in environmental investigations, develop standardized procedures, jointly conduct the investigations, and share all records and reports. FDA and CDHS established the CalFERT more than a year ago following investigations of other produce-associated disease outbreaks traced back to California products.

Over the week following September 14, information from the epidemiologic investigations going on around the country (including the outbreak strain being isolated from pre-packaged spinach first in New Mexico and ultimately in 13 different situations) narrowed the production dates in question. Work in the Natural Selections Foods facility rapidly resulted in the identification of nine farms or ranches in three counties that supplied spinach to the processing plant on the production dates implicated in the investigations. CalFERT team members began onsite field investigations within a week of the first notifications on September 14, 2006. As the investigation continued, the implicated date of pre-packaged spinach production was narrowed to August 15, 2006 during a single shift. Based on this information and a thorough review of records at the processing plant, the number of farms/ranches that supplied spinach for that day's production was narrowed to four locations in San Benito and Monterey Counties. From this point, the environmental investigation concentrated on spinach fields at these four locations. Two of the implicated fields had no produce growing on the date of the first visit. Produce on the other two fields was voluntarily disked under by the farmers. Produce has not been grown on those fields since.

Traceback and environmental investigations are a lot like detective work. The field investigators are trying hard to solve the mystery; to find out the who, what, when, where, and how of what happened to cause the outbreak. The environmental investigation seeks to identify all possible opportunities for introduction, survival, and growth of pathogens for the associated food vehicle. This includes detailed examination of growing, harvesting, shipping, processing, and final preparation/serving practices as well as testing of food handlers/food workers when appropriate. Unfortunately, these investigations rarely find a definitive source. The environmental investigations are extremely time-consuming (may take several investigators several months to complete) and may include investigations of dozens of sites/facilities (farms, distributors, wholesalers, brokers, manufacturers, retailers) and hundreds of environmental samples. The analogy we sometimes use is to "imagine trying to investigate a multi-vehicle auto accident 1 month after it occurred." Frequently, by the time the patients have been diagnosed and reported through the public health system, and the epidemiologic and laboratory investigations have implicated a particular food item, several weeks have passed. In fresh produce associated outbreaks, the fields have been replanted in a different crop, the harvest crews are long gone, and there are no more products to test from retail or consumer's homes.

The environmental investigation is conducted in a very standardized manner. The CalFERT team members have specific assignments, interview the farm management and workers utilizing farm investigation questionnaires, and systematically review the field environment and practices on the fields. They carefully documented all findings and conducted extensive environmental sampling for bacteriologic testing. The CalFERT team examined each field's surroundings, irrigation sources, wild and domestic animal presence, fieldworker hygiene, and collected samples. Domestic livestock operations were observed in the vicinity of three of the fields and fecal samples were obtained from these operations. A hydrology expert with CDC reviewed irrigation and obtained well and water management data for the properties. USDA Wildlife Services staff assisted the CalFERT team in investigating wildlife presence and conducted sampling.

E. coli O157:H7 was identified in fecal and/or water samples taken on or near all four fields. However, only one field has yielded the genetic testing matches to the outbreak strain of the bacteria. To date, 10 PFGE matches have been identified in cattle and wild boar feces, stream water, and intestinal content of a wild boar killed in the vicinity of this field. This particular field had features that concerned investigators even before sampling. The field is surrounded by hills and cattle pasture. Investigators saw extensive evidence of wild pig presence in and around the growing fields on the ranch (damage to fencing, burrowing under fencing, tracks, feces and evidence of rooting in produce fields) and established that numerous pigs thrive in the riparian habitat there. Potential avenues of contamination for the spinach crop may have included direct pig presence in the field or contaminated irrigation water, among numerous other possibilities. Investigators continue to investigate the source of the outbreak strain in the area. Since June 2004, USDA Agricultural Research Service working with CDHS has documented extensive periodic *E. coli* O157:H7 contamination in waterways in the greater Salinas Valley, though none of the isolates collected from these studies matched the spinach-associated outbreak strain. The

Salinas Valley appears to have systemic *E. coli* O157:H7 contamination in the environment that has led to a number of fresh produce associated outbreaks over time.

In total, more than 800 environmental samples have been collected by CalFERT in this investigation including soil, sediment, water, fecal material, feral pig tissue, drag swabs, plant material, and environmental swabs of harvesting equipment.

This outbreak was unusual in the widespread distribution of cases and in the virulence of the pathogen (more than 50 percent hospitalizations, three fatalities, and high rates of Hemolytic Uremic Syndrome in young and elderly patients). The investigation of this outbreak was unusual in the speed with which the traceback and environmental investigation was conducted to find a likely source of the contamination. The investigation illustrates the excellent working relationships between State and Federal public health agencies, and an effective use of the scientific tools now available in the study of these pathogens. What still remains to be done is to effectively implement what has been learned to prevent the next *E. coli* O157:H7 outbreak associated with fresh ready-to-eat produce.

FDA has documented 18 outbreaks of foodborne illness since 1995 caused by *E. coli* O157:H7 for which fresh or fresh-cut lettuce was implicated as the outbreak vehicle. In two additional outbreaks including the latest multi-state investigation, fresh-cut spinach was implicated. These 20 outbreaks account for approximately 610 reported cases of illness and five deaths. Although tracebacks to growers were not completed in all 20 outbreak investigations, completed traceback investigations of nine of the outbreaks associated with lettuce and spinach were traced back to California's Salinas Valley.

In 1998, CDHS provided technical assistance to FDA in the development of early guidance to industry entitled "*Guide to Minimize Microbial Food Safety Hazards for Fruits and Vegetables <http://www.foodsafety.gov/~dms/prodguid.html>*." This Guide recommends good agricultural practices (GAPs) and good manufacturing practices (GMPs) that growers, packers, and shippers may undertake to address common-risk factors in their operations, and thereby minimize food safety hazards potentially associated with fresh produce. In 1996, CDHS working with the lettuce industry developed voluntary agricultural production guidelines for lettuce. This document was used extensively in the development of the 1998 FDA GAPs document.

Following an outbreak of *E. coli* O157:H7 illnesses associated with California lettuce in 2002, CDHS began a series of meetings over the next 3 years with the lettuce industry to encourage the industry to "step forward," develop a comprehensive research plan to identify the likely causes of and possible preventive measures for the outbreaks, and commit significant long-term research funding to this plan. Unfortunately, these meetings did not result in the desired outcome and subsequent *E. coli* O157:H7 outbreaks have occurred.

CDHS has met with the leafy green industry on a number of occasions over the last 2 to 3 years to voice our concerns and to urge the industry to take the next step and develop a comprehensive research plan for identifying the cause of *E. coli* O157:H7 contamination in the fields and potential solutions, along with providing funding to jump start these efforts. We have worked with the industry, FDA, and academia to produce a video entitled "Safer Processing of Fresh Cut Produce." We have encouraged and participated in the formation of a "lettuce steering committee" at the Western Institute for Food Safety and Security at the University of California, Davis and I are developing a prioritized research agenda with this working group. We have met with FDA managers to voice our support for their open letters to the industry and our State health officer sent a letter to the California grower industry in January 2006 stating our support for FDA's approach, outlining several other areas that we plan to assess, and urging the industry to continue their recent commitment to solving this problem.

On February 5, 2004, FDA issued a letter to the lettuce and tomato industries to make them aware of concerns regarding continuing outbreaks associated with these two commodities and to encourage these industries to review their practices in light of FDA's GAPs/GMPs guidance and other available guidance. In view of continuing outbreaks associated with fresh and fresh-cut lettuce and other leafy greens, particularly from California, FDA issued this second letter to reiterate their concerns and to strongly encourage the lettuce industry to review their current operations in light of the agency's guidance for minimizing microbial food safety hazards in fresh fruits and vegetables, as well as other available information regarding the reduction or elimination of pathogens on fresh produce.

In April 2006, the lettuce and green leafy industry promulgated a *Commodity Specific Food Safety Guidelines for the Lettuce and Leafy Greens Supply Chain*. This document represents an excellent start towards Good Agricultural Practices that, if effectively and uniformly implemented at the farm level, could significantly reduce

the potential for bacterial contamination of fresh lettuce, spinach and other leafy greens. The Guidelines are relatively generic and lack specificity for consistent application on the farm. The next significant challenge for this industry and food safety experts is to put specificity and metrics to these practices so that they can be applied in a verifiable manner on all farms and ranches growing, harvesting and packing leafy green produce for consumption in order to assure improved food safety with these products.

In mid-summer 2006, FDA and CDHS Food and Drug Branch kicked off a joint lettuce safety initiative with Salinas Valley lettuce growers and processors to assess the use of the *Guidelines* and good agricultural practices on the farm, and good manufacturing practices in the processing plants. Although the initiative was in place for only a few weeks prior to being suspended with the onset of the multistate spinach-associated *E. coli* O157:H7 outbreak; preliminary findings on the farms showed that many growers were not implementing GAPs, and several were not aware of recommended GAPs.

We know where *E. coli* O157:H7 comes from. It is a common flora in cattle and perhaps in other ruminants, and can also be found in the gastrointestinal tracks of other wild and domestic animals. The risk factors for contamination of produce include water used for irrigation or possible from flooding, manure used for fertilization, field proximity to infected livestock, access to the fields by wildlife, and farm worker hygiene. Our job during the on-farm investigation is to determine where the fecal contamination came from, and how it ended up on the spinach or other fresh produce in the field. This latest investigation showed *E. coli* O157:H7 matching the outbreak strain in three of these potential sources. Although we may never be able to determine exactly what happened on the fields during or immediately before the harvest of spinach that went into the August 15 production lots at Natural Selections Foods, we can reinforce the idea that good agricultural practices implemented consistently every day on every farm growing fresh ready-to-eat produce will significantly reduce the risk for contamination. GAPs are of critical importance because we have witnessed that even the most state-of-the-art food processing can fail to remove *E. coli* contamination resulting in outbreaks. We do not know why that is the case, but it is. The best solutions for safer, fresh, ready-to-eat produce are research to better understand the ecology of these bacterial pathogens in the field and on the plants, the consistent application of Hazard Analysis and Critical Control Program based on good manufacturing practices in the processing and shipping environments, and universal application of GAPs on the farms and fields.

We still do not have a lot of science about the environment in which these products are grown, how and where pathogens may survive or grow in these environments, the effectiveness of various measures that growers can take to minimize the chances of contamination. What we do know is that there are still a lot of unanswered scientific questions about produce microbiology, how and where these pathogens survive or grow in the environment, and how traditional green leafy produce processing methods deal with low numbers of pathogens. More funding is needed for research in these areas.

The CHAIRMAN. Thank you. I'm kind of stunned by the previous testimony and your testimony regarding the length of time. Most of us don't have any idea of what has to go on when there is a problem. An additional one that you raised was that 21 to 32 people interviewed remembered days before that they ate spinach. I can hardly remember what I ate yesterday. I suppose if I was sick, I might have better recall—probably not. So there are definitely some difficulties with this whole process.

Now you mentioned that some fields have been disked under. How long until they can be used to grow spinach again? Can they ever be used again?

Dr. REILLY. That's part of our investigation, Senator. We are attempting to figure out what exactly happened there. Now these fields are not significantly different than another spinach field a mile up the road or maybe 20 miles up the road. A number of these are in valleys, a number of them have those risk factors I talked about, whether they have the opportunity for flooding, the opportunity for livestock or wildlife contamination. Some have better farm hygiene, farm worker hygiene than others. So the issue is not

so much exactly these fields. These are not the same fields that are responsible for the other 19 outbreaks that have occurred over time or the 9 that have occurred in Salinas Valley as a source of the spinach or fresh produce. We're trying to work with them. They are right now under an embargo order. They are not allowed to produce the product. If they do grow fresh product, we will embargo that product. We do not have a specific timeline for how long that order will last. We're trying to look into that to discover everything possible about what happened that may have predisposed these particular fields to be implicated.

The CHAIRMAN. Now you mentioned in your testimony that there were other fields that tested positive for *E. coli* but they weren't the outbreak strain. Have conditions or the possibility of embargo been placed on them, too? Your testimony says that *E. coli* is pretty common. So what is the dividing line between the embargo and not?

Dr. REILLY. That's an excellent question, Senator. We were investigating this outbreak. We traced back and found evidence of this actual strain type, the outbreak strain, on a single farm and we acted aggressively there to prevent that farm from bringing any produce to market. The other four farms, the investigation is ongoing. We have not, to date, identified the strain match, the genetic match. We have found a O157:H7, as you mentioned, on those farms as well. Our actions again, an attempt to try to protect the public's health. At this point, the season for growing spinach is very rapidly coming to a close in the Salinas Valley. They are transitioning to the southern portion of the State but we will be faced with the same question next spring, when those fields are again planted. We don't know why the ecology of the Salinas Valley predisposes to this contamination and it is not a unique finding. Over 2 years, we've found systematic contamination of the waterways in areas in the Salinas Valley with the O157:H7. There is still a lot of science that we don't know about as to why this is happening.

The CHAIRMAN. That's very distressing, since that is the salad bowl of the Nation. I'm glad you're on top of it. Now you indicated in your testimony that California didn't know about the outbreak until September 14, when it was announced publicly. But Dr. King stated that the outbreak was posted on PulseNet on September 8. Why the delay?

Dr. REILLY. We were not aware of the multi-state nature of the outbreak until the CDC and FDA pulled together the multi-state teleconference. We monitor PulseNet. We, as Dr. King mentioned, have several laboratories that feed into PulseNet. We had a single case that was matched, strain type matched. We discovered, I believe that day, that went up on the PulseNet.

Part of the usefulness of PulseNet is that it prompts further surveillance and targeted surveillance. One of the first things we did in California was to send notices to all of our public health officials in the State and out to providers as well, to start looking for this. If you see it—bloody diarrhea illness or illness compatible with O157:H7 to get that culture in right away and to try to look for this in order to document cases.

But frankly, we did not have cases that we had identified as part of the outbreak on the date that Wisconsin started. Over a couple days, that investigation matured and a second State came in. That is when FDA and CDC chose to put together that national teleconference to reach out and see what else was going on. Frankly, in the beginning of that teleconference, I think they were talking about 30 or so cases—by the end of the conference, it was 59, 60 cases. That's the nature of public health, collaborating to find out what information is available and then trying to target our efforts.

The CHAIRMAN. Thank you. Senator Burr, do you want me to call the other two up to the table at this point or do you want to ask some questions here?

Senator BURR. Mr. Chairman, I'd be happy just to ask a few questions first and then get everybody together if Senator Isakson wants to do the same. Dr. Reilly, welcome. California doesn't have a different set of standards for agricultural products, like leafy vegetables, than everybody else in the country?

Dr. REILLY. A different standard?

Senator BURR. Yes, I mean, you've got a different standard for everything else in California. I just find it incredible that there is not a higher standard as it relates to this.

Dr. REILLY. We certainly do have State laws that regulate processing. But we do not have specific laws on farm food safety.

Senator BURR. Trust me, I'm not challenging you to come up with any new ones. How do you clean up contamination from pig sites? Is that even possible?

Dr. REILLY. I don't know the answer to your question, Senator. It doesn't appear that *E. coli* O157:H7 is—that the pig is a definitive host. It's probably just an accidental host. It looks like this bacteria probably evolved in multichambered stomach ruminant animals—cattle, maybe other wild ruminants. How the pigs became infected, we don't know. You can use your imagination and figure out.

Senator BURR. Let me walk through the process and tell me if I understand the growth and processing process. The spinach is in a field. It's grown. It is irrigated from somewhere. That water applied to the spinach might cause a surface contamination of *E. coli*. But in California, like everywhere else, there is a washing process at the end of the process that has chlorinated water and maybe other things that is applied to leafy vegetables—and the specific intent is to kill any contamination.

Dr. REILLY. No, Senator. First of all, the processing of green leafy vegetables in the pre-packaged products that you see is regulated. There are good manufacturing practices that have utilized the concept of hazard analysis critical control point, trying to identify what are the potential critical control points where you can apply controls to prevent contamination. In the processing plant, that philosophy is used in the washing process, multiple washing processes and the use of high levels of chlorination—hypochlorite—in doing that rinsing. It is not designed as a kill step, though. It's not like cooking hamburgers to 160 degrees for a given period of time to kill the bacteria.

Senator BURR. So it's possible that you can have *E. coli* in the field as a surface contaminant and there is no process in those final stages that would kill that contamination. Correct?

Dr. REILLY. As of right now, the processing of fresh leafy green spinach or lettuce does not involve a kill step like that. The kill steps that traditionally would be used tend to change the nature of the spinach and it's no longer a fresh leafy green anymore, by heat or radiation.

Senator BURR. If the surface contamination did not take place in the field, could the surface contamination have happened in the washing process?

Dr. REILLY. That's certainly possible. In addition, contamination following processing is possible, whether it be on the supermarket shelves or in your kitchen or in a restaurant kitchen, cross contamination is probably responsible for most foodborne illnesses. But not in this case.

Senator BURR. Is it safe to say that if I open a bag of pre-packaged spinach and I wash it, I can't wash *E. coli* off of it?

Dr. REILLY. If there were *E. coli* contamination on the surface, you may not be able to reduce it to a level that would not cause you illness. Yes, you can reduce the levels. Whether you can make it safe—if it is already contaminated, we don't think so.

Senator BURR. Well, I'll save my last question until we get everybody up but you present us a scenario that I'm worried about. I was somewhat disturbed when we started because we were talking about a contamination that we don't understand yet. Now you've thrown a new kink into it—we may never know why the spinach was contaminated because there are multiple places that it could have happened and—I'm not soliciting an answer from you now. I'm pre-warning the other two but I will ask it. Is that the scenario that we're at? We don't know how. We know it got contaminated and it's likely we will never know exactly how it was contaminated. Thank you, Mr. Chairman.

The CHAIRMAN. Senator Isakson.

Senator ISAKSON. Really just one question. This reminds me, food safety has not been my business but I've been in the soil, sand and erosion control business for a long time and that being said, despite best management practices there are going to be gaps in any agricultural practice. You're going to have siltation and it sounds like you're going to have *E. coli*. The best thing is to have the best possible practices in place to prevent that from materializing into a problem. Is that correct?

Dr. REILLY. That's correct and we believe those good and best management practices can reduce it to a level where it will be very unusual or perhaps prevent these outbreaks from ever occurring.

Senator ISAKSON. And isn't it also—would this be a correct statement? It would seem to me likely that the producer of the spinach or a leafy vegetable has a high level of motivation to incorporate the best practices because they're going to suffer significant losses if they get a batch of their product that ends up being processed and has *E. coli*, is that correct?

Dr. REILLY. I would think so.

Senator ISAKSON. OK, last thing, just a question. In your statement, you basically say, we're going to have *E. coli*. It's out there.

We can try and use all these best practices but what we really need to do—there is no cure. We'd need more money for research. I think that was kind of what you said. My question is, is there current research going on—in milk, we have—in orange juice, you have pasteurization. Is there something going on with leafy vegetables?

Dr. REILLY. There is some research going on but in my opinion, not adequate. Simply being unable to answer a question as to what is the risk for internalization of this bacteria into freshly harvested produce or what potential is there for drawing bacteria up through the root system and what are some of the preventions that we could do there? That would help to inform what happens on the farm, during those harvest periods and reduce the risk even more. HACCP and good manufacturing practices, good agricultural practices are based on science. If they are going to work, they have to be based on science. We don't have enough science to base those on, to be comprehensive at this point.

Senator ISAKSON. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you. At this point, if I could have Dr. Brackett and Dr. King join us. I just have one important question for any legislation that we happen to be doing that I'd like all three of your opinions on. That is: are additional authorities needed to help you work together more effectively during an outbreak? Do we need another agency? What do we need?

Dr. Brackett.

Dr. BRACKETT. Well, as I mentioned during one of the questions here, that we have gained so much information from this particular outbreak and I've learned so much that we were in the process of looking, actually and sort of doing a hot wash of what would have worked, what wouldn't have worked in terms of would additional authorities have helped? Would they have not made any difference? And all of that, I think is going to be at the conclusion of the investigation when we try to figure this all out.

The CHAIRMAN. Thank you.

Dr. Reilly.

Dr. REILLY. I think that my principle observation is that this worked far better than investigations I've been involved with back over the last 12-plus years. The fact that USFDA and the Department of Health Services had some vision to put together a response team, where we've worked together versus independently, the fact that we had very routine conversations with the State health departments and agriculture as well, FDA and CDC was really visionary on their part. They did a great job of making this communication effective from the first day. So in my opinion, I think that we've done better here than ever before. Does that mean we can't do better? No. But I don't know that a change in organizational structure does that. It's a culture change that has been coming and has been maturing over time and I think this is evidence of maturation in our working relationships between the Federal and State agencies.

The CHAIRMAN. Thank you.

Dr. King.

Dr. KING. Yes, Senator. I don't have a position on it. I would say that the most important part is not going to—how many boxes or how many authorities there are but the relationship that work. I

think our work with, in particular, local and State health departments are absolutely critical in this. CDC is a nonregulatory agency. We would like to maintain that stature in terms of investigation. *E. coli* and some of these microbes could be presented in ways not through food and we still have to do those kinds of investigations so that one step of independence and objectivity, I think is critical from our point of view.

The CHAIRMAN. Thank you. Going back to our CDC expert, Senator Isakson, did you want to ask the three of them any questions?

Senator ISAKSON. I want to welcome Dr. King and I appreciate his tremendous contribution to the World's Health Center in Atlanta, Georgia at CDC. Thank you, sir.

The CHAIRMAN. We'll wait just a moment here until Senator Burr is back in the room. You have mentioned, particularly Dr. Brackett, some things that have been learned from this. If any of you have some suggestions, if you could get those to us as quickly as possible, we'll see what can be incorporated in anything that we do, so that we can have your best guess. I've always found that the best people to ask are those who are intricately involved in it on a daily basis. Sometimes that's a bit too common sense for us here but we'll live with it.

Senator Burr.

Senator BURR. My apologies, Mr. Chairman. Dr. King, let me go back to a statement that you made—you had seen X amount of cases of *E. coli* during this similar period. Were any of those cases the same type of cluster that you saw in Wisconsin?

Dr. KING. Let me give you a little bit of the context for that, Senator, if I may. We are constantly looking at matches in our system. In the last 10 years, PulseNet has 240,000 submissions. So that is what we have on file as a large computer base to look at. Two hundred and forty thousand. At the time that this spinach outbreak was getting going, we would see outbreaks of *E. coli*—cases of *E. coli* every day. One of the things I want to make sure I'm clear about, is that a cluster doesn't necessarily mean it's an outbreak. A cluster in one State is of interest to us. The real critical issue for us here was September 13, when we had a separate State with a large geographic distance with a match. Then we really got concerned. There may be, in summer and fall, 90 *E. coli* cases that we see a day reported to us. So the idea that we see one or two or three cases that may be a match is of interest and we monitor those. In this particular *E. coli*, O157:H7, we have seen cases of this particular microbe every month since 2003. So the idea of seeing a cluster of cases in one State, why of interest, does not trigger an outbreak or the kind of investigation that occurred on September 13. So this whole background of "it's not just *E. coli*"—it's salmonella. It's campolabactor. It's listeria, that we have to monitor and look at. So the system is open constantly. It's open for States to send in information.

Senator BURR. And I hope you understand. All I'm trying to understand is, what is that threshold at the CDC that says, "Whoops! This one goes right to the top of the list. We've got all this clutter over here that we've got to look at." That's our job. But what triggers part of that clutter to launch up in importance—the CDC is an important part of this whole process.

Dr. KING. Yes, sir. We realize that. And for us, the difference between a September 8 of a cluster in a single State that might have been a single source outbreak in Wisconsin, which was being investigated and rightly so. It was of interest to us. When another State got involved with a cluster of cases and there was a match. We say, "well how did a match occur in Oregon and at the same time in Wisconsin?" Then we knew that there had to be probably other sources and then we were concerned. That was the very day. That conference went out, that we contacted FDA that evening. FDA then, the very next day, came forward and talked to the public about potential threats of eating spinach. That's unprecedented in terms of the action.

Senator BURR. Let me go to Dr. Brackett, if I can. That correspondence happened and I'm going to play the what-if game. What if spinach processors and distributors had not cooperated and refused to pull spinach off the shelves and out of distribution centers—what could the FDA have done?

Dr. BRACKETT. Well, one of the first things is if we had any indication that the product was actually contaminated with the *E. coli*, we could have seized the product because it was adulterated under the Food, Drug and Cosmetic Act. So that's probably the first thing that could have been done. We also could have used one of the provisions in the Bioterrorism Act, which is withholding the product and getting it off the market that way as well.

Senator BURR. Your initial warning was much broader than leafy spinach. Going back through that, could that have been narrowed down any faster than it was?

Dr. BRACKETT. Well, we would have loved to narrow that down much faster. At the time, if you can put yourself in this situation, what we were seeing was information from the CDC where we had increases in the number of cases being reported, you know tens by daily or even hourly, all we knew is that they had consumed fresh bagged spinach and that's all we knew. It was happening across the country. There was a high virulence with it. We didn't know whether this would amount to 500 cases or 5 but we thought it was in the best interest of the public to warn them and make sure that the consumption stopped.

Senator BURR. In your opinion, the process that you had in place worked? The process at FDA—did it work?

Dr. BRACKETT. Yes, it did work. Our process, when we have outbreaks like this, is to work closely with CDC. When we get a true definition that there is an outbreak with food, we take whatever appropriate action, that would be enough in the case. If we happen to know a specific brand at that time, we'd have just notified the public or asked to recall that specific brand. But this was just so large, so fast and such a lack of information for the first few days that that's why we took that unprecedented action.

Senator BURR. Does the FDA need any additional power in this area to require growers, processors, and distributors to follow safer practices?

Dr. BRACKETT. Well, as Dr. Reilly said, the number—the general safety practices that we have, I think, are good and they are improving as we learn more about the ecology of this organism. At this point, as I mentioned to the Chairman, we're still trying to

look back and learn from this whole outbreak to find out if additional authorities at any points would have helped or whether they would have not made any difference at all. And once the whole investigation is over, we're going to put together some thoughts on that.

Senator BURR. One last comment, if I could and again, I want to thank all three of you for your willingness and your openness here and especially you, Dr. Reilly, because this was in your back yard. But I want to go to the heart of a statement that you made. You said that if all the growers followed good agricultural practices and I think you added good manufacturing practices, this might not have happened. I've gone to great lengths to try to figure out where this happened—a field, processing, water, soil, roots, surface and clearly, there's not enough known that anybody is willing to say, "here, this and that."

I'm not convinced today that if you just applied good agricultural practices and good manufacturing practices we would get no contamination, based upon what I've heard. And you can comment if you want to. I only point that out just to say that simply making sure that everybody applies to "X," not knowing how it happened, I'm not sure we get to an end result of no *E. coli* or no contamination.

Dr. REILLY. Senator, I believe that—well, first of all, we have good manufacturing practices in processing right now, across the country.

Senator BURR. But not all farmers apply it, not all processors apply it, is that an accurate——

Dr. REILLY. In processing, licensed processors—they practice good manufacturing practices. It's a mandate in California. I think it's a mandate in many other places, not everywhere. What we do not have is a mandatory program with good agricultural practices. I'm not recommending a mandatory program but I am recommending that we have systematically, from a cultural standpoint, that is the thing to do. If you are a grower, if you are a manufacturer of this product, that you are doing the best science-informed set of practices to reduce the risk. And that's all we could ask, is to reduce the risk. We know significant risk factors. We know some things that can reduce the opportunity for those significant risk factors to result in fecal contamination on the spinach field and *E. coli* to come with it.

We can only ask the manufacturer—rather, the growers in the field to do the same level of public health protection that we demand of our processing as well. There is a risk that is ongoing. Twenty outbreaks, 11 years. We have some tools to put into place to reduce that risk. Will it prevent every outbreak? Maybe not. But it will certainly reduce the risk.

Senator BURR. Again, I thank the three of you. I thank the Chairman for his indulgence.

The CHAIRMAN. Thank you very much and I too, thank the three witnesses for their time and particularly Dr. Brackett and Dr. King, for staying around to be a part of the questioning that came up from the local testimony that we had as well. So we thank you all for being here.

We'll move on to the third panel and I will introduce the witnesses all at once. They'll give their statements and then we'll move on to questions. I'm very excited to hear about the innovative products that have been developed by the members of this third panel.

For the panel, because of the time of day, I would hope that all of you would keep within the 5-minute presentation limit and maybe since we have full copies of what you wrote, if you're longer than that, perhaps you can summarize for us. Because you are the exciting part of this and I assure you that people will read to see what inventions there are out there. So if you would help us with that, that would give us some time for questions.

This is the order that people will be speaking in: Dr. Robert Whitaker, who is the President of MissionStar Processing, LLC, which is a contract, value-added vegetable processing company located in Salinas, California and Yuma, Arizona. MissionStar Processing is a joint venture between NewStar Fresh Foods and Missionero, two Salinas-based grower/shippers. The company was formed in early 2006 to process both companies' valued-added conventional and organic salads. MissionStar produces a wide array of Spinach Spring Mix and Blended Baby Leaf salads and specialties for food service distributors and private label products for a number of retail customers. Dr. Whitaker received his Ph.D. in Biology from the State University of New York at Binghamton in 1982. Dr. Whitaker will discuss the impact of the recall on his business and what could be done in the future to prevent or contain outbreaks associated with fresh produce.

Ms. Terri-Anne Crawford is Vice President and Chief Operating Officer of Franwell, Inc. Franwell has more than 10 years invested in research and development of radio-frequency identified technologies—RFID. Franwell is an Associate Member of the University of Florida Research Center for Food Distribution and Retailing, which is CFDR, and is engaged in an ongoing project testing the use of radio frequency identification technology as it relates to each link of the food supply chain. Prior to joining Franwell, Crawford worked for Publix Supermarkets for 23 years, where she was responsible for the development of Publix RFID strategy and worked with the University of Florida to design and deploy the V2 Project, which is testing the benefit of using the EPC Global Network and the fresh produce supply chain. She'll discuss how RFID technology can be used to track and trace food products and facilitate a recall in the event of an outbreak.

Mr. Jeff Palmer is President and General Manager of DayMark Safety Systems, a company of 140 employees that has experienced 900 percent growth under his leadership. Mr. Palmer became Manufacturing Manager for both DayMark and Century Marketing in 1992 and General Manager of DayMark in 1999. Much of DayMark's success was due to the innovation and introduction of Dissolve-A-Way label technology. Mr. Palmer and his team were an Ernst & Young Entrepreneur of the Year finalist in 2002. Mr. Palmer is a graduate of Florida Tech and a member of the International Food Service Manufacturing Association. Mr. Palmer will discuss how time and temperature abuse are the two biggest fac-

tors in foodborne illness outbreaks and how DayMark's TimeStrip product can help manage those factors to prevent outbreaks.

Mr. John Vazzana is President and CEO of Intralytix, Inc. Mr. Vazzana has over 35 years of business experience and he has been instrumental in transforming startup or small companies into profitable, publicly traded corporations. He received a Bachelor of Science from the University of Maryland in 1968, with a major in accounting. Yes! I'm the only accountant in the U.S. Senate. Mr. Vazzana will discuss the bacteriophage technology his company developed to kill listeria bacteria on ready-to-eat meats. The technology was recently approved by the FDA. Congratulations on that.

Dr. Whitaker, you may begin.

STATEMENT OF DR. ROBERT WHITAKER, PRESIDENT, MISSIONSTAR PROCESSING, SALINAS, CA

Dr. WHITAKER. Good afternoon, Mr. Chairman, Senator Burr and Senator Isakson. My name is Dr. Robert Whitaker and I am President of MissionStar Processing, a value-added, fresh cut vegetable processing company based in Salinas, California. MissionStar Processing is a joint venture of Salinas grower/shippers New Star Fresh Foods and MissionArrow Vegetables, to process their value-added organic and conventional fresh salads.

Our company produces a variety of spinach, spring mix and blended baby leaf salads and specialties for food service distributors and private label products for a number of retail customers. I am also the immediate past Chairman of the International Fresh Cut Produce Association, which recently merged with the United Fresh Fruit and Vegetable Association to form United Fresh Produce Association or United Fresh. Together, we have combined forces to deliver the highest level of food safety and scientific expertise to our industry.

First let me address the human impact of illnesses associated with this outbreak. We cannot ever forget that more than 200 people in 26 States became seriously ill and three people died, directly from eating one of our industry's healthiest products. Any one of us in the business of growing, marketing and selling ready-to-eat foods must embrace the importance of our own personal actions in reducing the risk of that happening again.

Two months ago, the FDA took the unprecedented action to advise consumers not to consume any fresh-bagged spinach. That advice arose from the immediate concern that a serious *E. coli* O157:H7 foodborne disease outbreak was underway and that government officials could not tell exactly where the contaminated product might be in the marketplace. Unlike a traditional food recall of only one product that was directly implicated in an outbreak, the FDA felt the proper caution required warning consumers against an entire produce commodity category.

In hindsight, we now know a whole lot more about the scope and source of the outbreak. The FDA has since confirmed that all contaminated product in this outbreak was produced in one processing plant, indeed, in 1 day. All spinach processed in the plant on that day came from four farms. While we continue to investigate exactly how that contamination might have occurred, we know that contamination was limited to a very small part of the fresh spinach

supply. Only product that was processed by one company and from 1 day's production.

Yet, despite the actual narrow cause of the outbreak, the entire fresh spinach industry has suffered a tremendous blow. Growers and processors of fresh spinach that had perfectly safe product in the marketplace, including my company, pulled our product from retail shelves, warehouses, processing plants, and even stopped harvesting. I am proud of the way our entire industry responded to FDA's immediate concern but I'm also concerned that we did not collectively narrow this outbreak and communicate to all consumers that it was safe to consume spinach that was not implicated in the recall.

Two months later, we are all still suffering from a loss of market confidence due to fears about general spinach safety that were unwarranted by the facts of the outbreak.

Looking to ways to prevent future outbreaks, let me state clearly that food safety is the produce industry's very top priority. Our industry has an extraordinary safety record providing American consumers over 6 million bags of fresh salad every day. But we are committed to further reducing any risk associated with our products. We are constantly working to enhance and improve our performance in growing crops in the field, carefully harvesting and handling them for distribution, packaging and processing commodities into convenient ready-to-eat products and maintaining the safest possible delivery chain all the way to the consumer's table.

For example, our farmers are strongly urged to follow good agricultural practices or GAPs as we've heard them called today that have been reviewed by academic scientists and regulatory officials to help assure fresh produce safety. My company, MissionStar and our colleagues in the fresh cut processing of produce follow strict food safety systems in their processing plants, including rigorous HACCP or hazard analysis critical control point systems and GMPs, your good manufacturing practices, to prevent food contamination from occurring.

In the fresh processing plants, produce companies take special precautions, such as removing dirt or other contaminations that can be sorted out and found. Raw product then goes through a vigorous washing process in the plant, often rinsed three times in chlorinated water to help ensure the product is clean and free of pathogens, then careful temperature controls monitored throughout the distribution chain, shipping produce in refrigerated trucks to retail markets and restaurants.

It is critical that we begin to look at lessons learned from this episode, work with Congress, FDA, CDC, USDA and others to find the right tools to prevent future outbreaks and minimize the damage to whole food categories, should a similar situation unfold in the future. Federal research dedicated specifically to fresh produce food safety is vital to making advancements in preventing future foodborne outbreaks associated with produce commodities.

Unfortunately, current funding is not sufficient to tackle the urgent need for additional research. For example, in fiscal year 2006, USDA ARS discretionary funds available for intramural fresh produce food safety research were only about $2 million. USDA CSREES has funded only about $2.5 million in extramural fresh

produce food safety projects in the past 5 years. At FDA CFSAN, which in prior years has had discretionary funding available for targeted intramural and extramural food safety research, we understand that no money is now available for fresh produce food safety research. Therefore, research funding dedicated specifically to fresh produce food safety is a top priority of the produce industry.

Finally, in looking at the impact of this outbreak, we believe a very important principle is at stake. Companies must not be penalized for doing the right thing when asked by public health agencies. Legally, spinach growers and marketers that were not subject to this food recall were perfectly in their right to keep selling product but they followed the direct request from FDA to help consumers avoid all spinach when it was unclear where a contaminated product might have been in the market. Yet these companies, my company, suffered significant financial losses, even though we are not in any way implicated in this outbreak. Ironically, those companies whose products were not implicated in a food recall may not be insured for their losses. The extraordinary circumstances surrounding this outbreak should leave the Congress to consider compensation for those who suffered losses, pulling safe and healthy spinach from the marketplace. There is ample precedent for compensating businesses when government action has forced an expensive, private action for the sake of public health. We urge you to consider this important principle.

In conclusion, Mr. Chairman, one of the major lessons we must learn from this is that our entire industry faces this food safety challenge together. It should be abundantly clear that outbreaks don't just affect the one company who introduces the product to the market or the one sector of the industry or the one single commodity or one single region. Our entire industry is dependent upon our weakest link.

We look forward to working with you and the committee in the coming months as we constantly seek ways to enhance the safety of the food supply and bring Americans great tasting, healthy and safe fresh fruits and vegetables that help improve their health. Thank you, sir.

[The prepared statement of Dr. Whitaker follows:]

PREPARED STATEMENT OF ROBERT J. WHITAKER, PH.D.

INTRODUCTION

Good afternoon Mr. Chairman and members of the committee, my name is Dr. Robert Whitaker and I am President of MissionStar Processing, a value-added fresh-cut vegetable processing company based in Salinas, California. MissionStar Processing is a joint venture of Salinas grower-shippers NewStar Fresh Foods and Misionero Vegetables to process their value-added organic and conventional fresh salads. Our company produces a variety of spinach, spring mix and blended baby leaf salads and specialties for foodservice distributors and private label products for a number of retail customers.

I received my Ph.D. in biology from the State University of New York at Binghamton in 1982, and have spent my career in microbial and plant biochemical genetics, the use of biotechnology to develop new plant varieties, and management of food safety/quality assurance operation in the processing of fresh value-added vegetables. In the past 5 years, I have been responsible for overall process operations of our company's processing business and overseen the construction of two state-of the-art value-added vegetable processing facilities.

I am also the immediate past chairman of the International Fresh-cut Produce Association, which recently merged with the United Fresh Fruit & Vegetable Association to form United Fresh Produce Association (United Fresh). Together, we have combined forces to deliver the highest level of food safety and scientific expertise to our industry. Our association is led by a Board of Directors representing leaders from every sector of the industry, a 50-member Food Safety and Technology Council including scientific experts from our member companies, and an expert staff food microbiology, plant sciences, nutrition and health, and much more.

I want to compliment the committee today for holding this very timely hearing given the ongoing focus on food safety across the industry, and the collective response of government and industry to the recent *E. coli* O157:H7 foodborne disease outbreak associated with one fresh spinach product.

First, let me address the human impact of illness associated with this outbreak. We cannot ever forget that more than 200 people in 26 states became seriously ill, and several died, directly from eating one of our industry's healthiest products. The consequences of that fact alone are huge, and any one of us in the business of growing, marketing and selling ready-to-eat foods must embrace the importance of our own personal actions in reducing the risk of that happening again.

That is a commitment that my company and our entire team of officers and associates take seriously every day, and it is a commitment that our entire industry is making to consumers of our products. Growers, processors, retailers, restaurants and trade associations that represent our companies across this industry will simply do everything we know how to minimize the risk of something like this happening again. As scientists, we know that one cannot achieve zero risk with anything in life, but we will work hard to drive risk as low as possible.

INDUSTRY IMPACT

The committee asked me to share some sense of the impact of this outbreak on our business and the industry, and provide thoughts on ways to prevent or more quickly contain future outbreaks.

Two months ago, the FDA took the unprecedented action to advise consumers not to consume any fresh bagged spinach. That advice arose from the immediate concern that a serious *E. coli* O157:H7 foodborne disease outbreak was underway, and that government officials could not tell exactly where the contaminated product might be in the marketplace. Unlike a traditional food recall of only product that was directly implicated in an outbreak, FDA felt that proper caution required warning consumers against an entire produce commodity category.

Why did FDA issue such a broad warning? At the outset, CDC and FDA were faced with a terrible mass of confusion—strong evidence of a growing outbreak of serious illness and possible death, strong circumstantial evidence linking it to fresh bagged spinach, but with confounding factors of several different brands and many different days of production potentially implicated by bagged product still in patients' refrigerators. The public health agencies acted in their best knowledge to protect public health.

With the benefit of hindsight, we now know a whole lot more about the scope and source of the outbreak. FDA has since confirmed that all contaminated product in this outbreak was produced in one processing plant—on 1 day. All spinach processed in the plant on that day came from a maximum of four farms. While we continue to investigate exactly how that contamination might have occurred, we know that contamination was limited to a very small part of the fresh spinach supply—only product that was processed by that one company from one day's production.

Yet, despite the actual narrow cause of the outbreak, the entire fresh spinach industry has suffered a tremendous blow. Growers and processors of fresh spinach that had perfectly safe product in the marketplace, including my company, pulled our product from retail shelves, warehouses, processing plants, and even stopped harvesting. I am proud of the way our entire industry responded to FDA's immediate concern, but also concerned that we did not collectively narrow this outbreak and communicate to consumers that it was safe to consume spinach that was not implicated in the recall. Two months later, we are all still suffering from a loss of market confidence due to fears about general spinach safety that were unwarranted by the facts of this outbreak.

We strongly urge the committee to work with FDA, CDC and other agencies to more quickly limit the scope of concern in an outbreak such as this. Long-term, public health will not be well-served by consumers losing confidence in entire fresh produce categories because we fail to limit the damage when something does go terribly wrong with one company's products.

PRODUCE INDUSTRY'S FOOD SAFETY FOCUS

Looking to ways to prevent future outbreaks, let me state clearly that food safety is the produce industry's very top priority. We strive every day to bring fresh fruits and vegetables to consumers around the world that are safe, wholesome, nutritious and great-tasting. We are constantly working to enhance and improve our performance in growing crops in the field, carefully harvesting and handling them for distribution, packaging and processing commodities into convenient, ready-to-eat products, and maintaining the safest possible delivery chain all the way to the consumer's table. Our food safety commitment runs from field to table, and requires the active management of every player along the distribution chain.

Food safety is a process of continuous improvement for our industry, and we are constantly striving through industry and government research and process operations improvement to further reduce any potential risk.

• Our farmers in the field are urged to follow strict "Good Agricultural Practices" (GAPs) that are reviewed by academic scientists and regulatory officials to help assure fresh produce safety. Today, we are in a constant process to update, strengthen and quantify these practices for specific commodities.

• My company MissionStar and our colleagues in the fresh-cut processing of produce follow strict food safety systems in their processing plants, including rigorous HACCP (Hazard Analysis Critical Control Point) systems and GMPs (Good Manufacturing Practices) to prevent food contamination from occurring.

• In these fresh processing plants, produce companies take special precautions, such as removing dirt or other contamination that might be found. Raw product then goes through a vigorous washing process in the plant, often rinsed three times in chlorinated water, to help ensure the product is clean and free of pathogens.

• Then, careful temperature control is monitored throughout the distribution chain, shipping produce in refrigerated trucks to retail markets and restaurants.

• Because fresh produce is often consumed uncooked in its raw state, everyone handling produce must prevent cross-contamination from raw or undercooked meats, used cutting boards, and even dirty hands that may be carrying bacteria. The produce industry is a strong supporter of the government-industry Partnership for Food Safety Education, which sponsors the Fight BAC food safety consumer education initiative.

Our goal when it comes to food safety is that no one would ever become sick from consuming our products. We take our responsibility seriously to provide the safest possible foods to each and every consumer every day. That is an enormous task when you consider what it takes to feed America's produce consumers. While we are proud of our safety record in producing some 6 million bags of salad for Americans every day, we will never be satisfied if even one consumer gets sick from eating our products.

NEXT STEPS

It is now critical to begin to look at lessons learned from this episode, working with Congress, FDA, CDC, USDA, and others to find the right tools to prevent future outbreaks, and to also minimize the damage to whole food categories should a similar situation unfold in the future.

Federal research dedicated specifically to fresh produce food safety is critical to making advancements in preventing future foodborne outbreaks associated with produce commodities. Over the years, the congressional agricultural appropriations budget has been the primary source of funding for such research. In addition, USDA has the ability to allocate critical funding targeted at fresh produce food safety through several different research arms, mainly CSREES and ARS. Unfortunately, current funding is not sufficient to tackle the urgent need for additional research.

For example, in fiscal year 2006, USDA ARS discretionary funds available for intramural fresh produce food safety research were only about $2 million. USDA CSREES has funded only about $2.5 million in extramural fresh produce food safety projects in the past 5 years. At FDA CFSAN, which in prior years has had discretionary funding available for targeted intramural and extramural food safety research, we understand that no money is now available for fresh produce food safety research.

Therefore research funding dedicated specifically to fresh produce food safety is a top priority of the produce industry. In particular, these funds could be distributed among the Federal food safety research organizations which already have the appropriate infrastructure for further targeted distribution of the funds. These include:

• USDA ARS National Program 108 Food Safety that would be further distributed to ARS Research Centers and the National Alliance for Food Safety and Secu-

rity. These entities already constitute the top U.S. researchers in the area of fresh produce food safety.

• USDA CSREES, distributed through National Research Initiative's Food Safety (32.0) and Epidemiological Food Safety (32.1) programs. This funding should be applied to the examination of microbial ecology and control as it relates to the introduction, spread and persistence of *E. coli* and other human pathogens in the production, processing and packaging of foods.

• Funding for FDA CFSAN could be utilized for laboratory and field food safety research related to areas in which FDA has greater historical understanding and involvement, such as post-harvest processing operations, transportation and distribution, and product handling at retail and foodservice operations. In addition the industry would support the establishment of the FDA Center Food Safety Excellence to be housed at the Western Institute for Food Safety and Security Center in UC Davis.

Finally, please allow me to raise one important point that may be beyond this committee's purview, but is an essential issue for the Congress.

In looking at the impact of this outbreak, we believe a hugely important principle is at stake—companies must not be penalized for doing the right thing when asked by public health agencies. Legally, spinach growers and marketers that were not subject to this food recall were perfectly in their right to keep selling product. But, they followed the direct request from FDA to help consumers avoid all spinach when it was unclear where contaminated product might be in the market. These companies—my company—suffered significant financial losses even though we were not in any way implicated in this outbreak.

How do I explain to my owners that all the expensive investments we've made in food safety in our own growing operations and processing plants did not prevent us from suffering the same losses as those directly implicated? This was a *de facto* recall across an entire industry, although the entire industry was not responsible for introducing contaminated food into commerce. And ironically, many companies in my industry appear not to be covered by insurance, simply because they were NOT part of the formal recall.

Many suggest that the extraordinary circumstances surrounding this outbreak should lead the Congress to compensate those who suffered extraordinary losses pulling safe and healthy spinach from the marketplace. There is ample precedent for compensating businesses when government action has forced an expensive private action in the sake of public health. We urge you to consider this important principle as well.

CONCLUSION

Mr. Chairman, one of the major lessons we must learn from this is that our entire industry faces this food safety challenge together. It should be abundantly clear that outbreaks don't just affect the one company who introduces product to the market, or one sector of the industry, or one single commodity, or one single region. Our entire industry is dependent upon our weakest link—our lowest common denominator.

Growers must realize that we are growing ready-to-eat products that are consumed raw. Processors must realize that due diligence means personally knowing your raw product has been grown to meet the highest agricultural standards, and then employing state-of-the-art processing technologies. Retailers and foodservice companies must realize that food safety costs money, and when they want to buy safe foods, they must pay for safe foods. And consumers must count on the government and private sector to work together to bring the very best science available to ensuring food safety, without the false illusion that anything can ever be 100 percent without some risk.

We look forward to working with you and the committee in the coming months as we constantly seek ways to enhance the safety of the food supply and bring Americans great tasting, healthy and safe fresh fruits and vegetables to improve their health.

The CHAIRMAN. Thank you.

Ms. Crawford.

STATEMENT OF MS. TERRI-ANNE CRAWFORD, VICE PRESIDENT AND CHIEF OPERATING OFFICER, FRANWELL, INC., PLANT CITY, FL

Ms. CRAWFORD. Mr. Chairman, Senator Burr, thank you for the opportunity to testify today and thank you for your attention to the

issue of food safety and your interest in health technology can be deployed to potentially help contain outbreaks of foodborne illness and particularly facility recalls when an issue is discovered.

I'd like to focus my statement today on three specific areas that highlight how IT solutions are being developed and could potentially be used to improve food safety and recalls.

The first involves using a shared network of information to track the movement of food through the supply chain. The second involves using RFID to facilitate the capture and accuracy of the information within that network. Finally, the third involves the use of RFID enabled temperature tracking devices to monitor the handling of product throughout the supply chain.

As Senator Enzi pointed out, I'm from Franwell. Franwell is a technology development company based in Plant City, Florida. We offer technology products and services primarily to the food and pharmaceutical industry. We have a particularly close affiliation with the fresh food industry. We're also a technology partner for the Georgia Tech Research Institute and as you pointed out, the University of Florida's Center for Food Distribution and Retailing. Franwell is also an active member of several industry groups, including United Fresh Fruit and Vegetables.

I joined Franwell in March of this year. Prior to that, I was with the Information Technology Department at Publix for 23 years and in my career there, I was responsible for all the strategic planning and implementation of all the technology in Publix eight distribution centers and 24 warehouses. So I have extensive background in supply chain management.

Now to get back to today's topic and the points I would like to make. First, tracking product through a shared network. Before food product reaches your dinner table, it has been through an expansive supply chain with many links along the way. Imagine the journey your bagged salad takes. Starting in the field, lettuce and spinach is harvested and then taken to a processing plant. Once processed, it is then placed in a distribution center, loaded on to a truck, only to end up in another distribution center and on another truck before it ends up on your grocery shelf. Trust me, that's the short route.

Is all this movement easy to track? Well, quite frankly, no. In today's supply chain, the individual links do a fair job of tracking the product within the confines of their organization and their own inventory tracking systems. But load that product on a truck destined for another company and you've just lost visibility of the product. When it arrives at its new destination, it begins a whole new life within the confines of their inventory tracking system, with very little—if any—ties to its roots.

In order to execute any large-scale recall in a timely manner, the real key is an infrastructure that provides a network of shared data about product and its life cycle. If the shipment data about the product is available in a shared network, that product can quickly and efficiently be tracked and removed from the supply chain. Ideally what you want to happen is, all the tainted product is quickly removed, safe product is still available and the result is less loss to the industry and prevention of the more devastating loss of lives.

Franwell has been involved in an RFID trial led by the University of Florida CFDR. The goal of this research project has been to prove the viability of sharing this level of information across the supply chain. The project is called, Visibility Validated or V2. The project tracked shipments from three fresh produce suppliers, one of them coincidently, in Salinas, California, to a retailer's produce distribution center. Although on a small scale, the research project demonstrated that it is possible to use a network to share this data among trading partners.

Next I will address using RFID for the accurate and efficient data capture. I said earlier that companies do a pretty good job of tracking product within their own organizations. But many of the processes today are manually intensive and when data is captured manually, mistakes can be made. RFID technology involves placing a tag on product cases that contain a tiny computer chip and an antenna. The antenna enables the chip to transmit information to a reader and then pass it to a computer that can make use of it. This does not require contact between the reader and the tag.

RFID technology is not new. It's been around since World War II. What is new is the mainstream use of RFID that we've come across every day. RFID is used for automated toll payment systems, ID badges with secured entry to buildings and even on the Metro system.

So when used on product cases, the RFID tag contains information about the product, primarily the electronic product code or EPC. The EPC is unique to each case of product and is used to look up or update information about that case of product in computer systems and shared networks. The unique code allows us to identify one case of produce from another. Once applied, the RFID tags can be read at key points in the supply chain, from trading partner to trading partner. I'm sure you can imagine how much more valuable it is to identify product by a serialized code. Keep in mind, that for this information to be useful, it still requires a shared network of data, which contains the information about all the active electronic product codes within the entire supply chain.

The technology is not yet perfect but progress is made everyday due to the efforts of universities, research labs and private companies alike.

Finally, I'd like to talk about using RFID tags for temperature monitoring. Monitoring the cool supply chain with RFID temperature monitoring devices is another area where Franwell and the Center for Food Distribution and Retailing are actively engaged. Temperature is the characteristic of the distribution environment that has the greatest impact on the storage life and safety of fresh food. Good temperature management is, in fact, the most important and yet is the simplest procedure for delaying product deterioration and preserving product quality and safety.

RFID can be combined with temperature monitoring devices to allow full visibility of a product's life cycle through the cold chain in real time. Although *E. coli* is not a result of poor temperature management, other health concerns are a direct result of temperature abuses. RFID devices offer standard interpretation of data and the read can be automated with the same readers that are capturing other information about the product.

Information technologies can be used in many ways to make the supply chain more efficient and safer but for these systems to be effective, they have to be interoperable and for that, we need industry-wide standards. If we're going to have an effective RFID track and trace system to facilitate product recalls, it has to be uniform from one company to the next and in today's global environment, it has to be uniform from one country to the next.

In some cases, the industry has done a very good job in producing widely accepted standards. In other cases, it is important for government to play a leadership role. It is not easy and it can be a long and difficult process but standardization is critical to widespread implementation of any new technology and those standards must stretch beyond company and country borders.

Congress and the Administration can help by encouraging the FDA and USDA to work with standards groups. Federal Government can also help by sponsoring research efforts, such as the work being done at the University of Florida and other universities as well as private technology companies.

Finally, the Federal Government needs to reinforce to private industry the importance of cooperating on standards and that track and trace of product and ensuring a safe food supply should never be a reactive afterthought.

Thank you for the opportunity to testify today.

[The prepared statement of Ms. Crawford follows:]

PREPARED STATEMENT OF TERRI-ANNE CRAWFORD

Mr. Chairman and Mr. Ranking Member, thank you for the opportunity to testify today. And thank you for your attention to the issue of food safety and your interest in how technology can be deployed to potentially help contain outbreaks of foodborne illness and, particularly facilitate recalls when an issue is discovered.

I'd like to focus my statement today on three specific areas that highlight how IT solutions are being developed and could potentially be used to improve food safety and recalls. The first involves using a shared network of information to track the movement of food throughout the supply chain. The second involves using RFID to facilitate the capture and accuracy of the information within the network. Finally, the third involves the use of RFID-enabled temperature tracking devices to monitor the handling of product throughout the supply chain.

Before elaborating on these points, let me first tell you a little about my company and my background. Franwell is a technology development company based in Plant City, Florida (in the process of relocating to Lakeland, Florida). We offer technology products and services to the food and pharmaceutical industries, with a particularly close affiliation with the fresh food industry. We offer RFID integration services to many diverse industries and have developed and deployed RFID applications to improve product tracking in the supply chain.

We are a technology partner with the Georgia Tech Research Institute (GTRI) and University of Florida's Center for Food Distribution and Retailing (CFDR). We started RFID research with GTRI in 1993 and continue to work with their signal engineers on developing new products and overcoming RFID challenges. Franwell is an Associate Member of the CFDR, and is responsible for the contribution, installation and maintenance of RFID technology used in the center's RFID lab. Franwell also serves as a technology partner for many of the Center's research initiatives. The mission of the CFDR is to provide the food industry and the scientific community with a unique environment for developing knowledge that will assure food quality and safety throughout the whole distribution chain. In addition to our involvement with academia, Franwell is also an active member of industry groups, such as EPCglobal, the Cool Chain Association, United Fresh Fruit and Vegetable Association (UFFVA), and Produce Marketing Association (PMA).

I joined Franwell in March of this year, prior to joining Franwell I was with the Information Technology Department at Publix Super Markets for 23 years. The last 13 years of my career there, I was responsible for the strategic planning and implementation of all technology in Publix's distribution centers and warehouses, pro-

viding technology to run more than 8 distribution centers and 20 warehouses, shipping product to more than 900 stores. I was also responsible for researching RFID in order to determine a corporate strategy for implementation of the technology at Publix.

Now to get back to today's topic and the points I'd like to make.

TRACKING PRODUCT THROUGH A SHARED NETWORK

Before a food product reaches your dinner table, it has been through an expansive supply chain with many links along the way. Imagine the journey that your bagged salad takes—starting in the field, lettuce or spinach is harvested and then taken to a processing plant, once processed it is then placed in a distribution center, loaded onto a truck, only to end up in another distribution center and on yet another truck before making it to your grocery shelf. And this is the short route, assuming no secondary processing plants, additional distribution centers, or consolidation centers are involved and not to mention the added journey that imported product takes. Is all this movement easy to track? Well, quite frankly, no.

In today's supply chain, the individual links do a fair job of tracking the product within the confines of their organization and their own inventory tracking systems, but load that product on a truck destined for another company and you have just lost visibility of the product, where it came from and where it is going. When it arrives at its new destination it begins a whole new life within their inventory tracking system, with very little, if any ties to its roots. In the case of a foodborne illness outbreak or any other need for recall, the thing that is missing is complete visibility of where any of the tainted product is within a complex supply chain that is in constant movement every minute of every day.

In order to execute any large-scale recall in a timely manner, the real key is an infrastructure that provides a network of shared data about product and its life cycle. If the shipment data about product is available in a shared network, showing where every occurrence of a particular lot of product is located, that product can quickly and efficiently be removed from the supply chain. Ideally, all tainted product is quickly removed and safe product will still be available, resulting in less losses to industry and in the case of foodborne illness, preventing the even more devastating loss of lives.

Franwell has been involved in an RFID trial led by the University of Florida's CFDR. The goal of this research project has been to prove the viability and value of sharing this level of information across supply chain trading partners. Dubbed Visibility Validate or V2, the project tracked shipments from three fresh produce suppliers to a retailer's produce distribution center. Data about the shipment and receiving of product was posted to a shared network and everyone involved had access to the data via the Internet. Although only one product code was tracked from each of the suppliers, the research project demonstrated that it is possible to use a network to share this data among trading partners.

This type of research is very important and needs to be expanded. We need to prove it can scale to support the enormous amount of data that would be collected once many or all products were being tracked through a network. There also needs to be continued effort on defining exactly what information is the most important to capture, at what points in the supply chain, and the technology needed for this much data to be aggregated and accessed efficiently.

RFID FOR ACCURATE AND EFFICIENT DATA CAPTURE

I said earlier that companies do a pretty good job of tracking product within their own organizations, but even to track the product internally, many of the processes today are manually intensive. Introducing new points for capturing this data can be very costly due to the manual nature that is used to do so. When tracking product from the field to a processing plant or distribution center, there are many steps along the way and when this data is being captured manually, mistakes can be made.

RFID technology involves placing a tag on product cases that contain a tiny computer chip and an antenna. An RFID reader or scanner is a proximity reader, which means it does not require contact between the reader and the tag. This ability to read the information from the tags without line-of-sight or direct contact is the primary advantage of RFID tags for identifying product. The antenna enables the chip to transmit information to a reader. The reader converts the radio waves returned from the RFID tag into a form that can then be passed to computers that can make use of it. RFID technology is not new; it has been around since World War II. What is new is the mainstream use of RFID technology that we witness every day. RFID

is used for automated toll payment systems, ID badges, secured entry to buildings, and even for transportation on the Metro System.

When used on product cases, the RFID tag contains information about the product; standards call for an Electronic Product Code or EPC. The EPC is unique to each case of product and is used to look up or update information about that case of product in computer systems and shared networks.

For example, today if you purchase a 16 oz. can of green beans, there is a bar-code on that can. The can came out of a case, and there was a barcode on the case. The bar-code actually contains a Global Trade Identification Number, known as a GTIN, which identifies what that product is. Every 16 oz. can of green beans from a particular manufacturer will have the exact same GTIN. Scanning the bar code will tell you the product and can be connected to information systems to provide information such as the price or inventory count, but it won't give you any unique characteristics about that particular can or case of cans. The EPC on the other hand, is designed to identify not only the product, but a particular instance or occurrence of the product by including a serialized code along with the GTIN.

I am sure you can imagine how much more valuable it is to identify a product by a serialized code, rather than just knowing where all canned green beans are, you could know where all the cans of green beans, processed on a particular day by a certain manufacturer are. Keep in mind, that for this information to be useful to track and trace product, it requires a shared network of data which contains information about all the active Electronic Product Codes within the entire supply chain.

In addition to the value of the EPC and a shared network, RFID adds value through automation. Today, much of the process for tracking product harvested from the field is captured on paper and paper records are notoriously error-prone. Even if the information is ultimately entered into a computer system, handwriting is hard to read, pages get lost, data-entry falls behind or the information gets keyed incorrectly.

With RFID, cases or totes could be tagged with a unique EPC before being taken into the field at harvest. By knowing which totes are taken to which area or field, those EPCs could be associated with the harvester and the field. Or a more flexible method would be to have handheld RFID readers right out in the field and associating the EPC on the case or tote with that product from that field on that day and time. GPS technology could even be added to validate the exact harvesting location. When the cases packed in field are the actual cases that will ultimately be shipped to your local grocery store, this same RFID tag can be used to track the product through its entire journey. If product is harvested and sent for further processing, then the tracking would have to continue through processing and be associated with a new EPC tag applied to the finished product, say a case of bagged salad.

Once applied, the RFID tags can be read at key points in the supply chain and the network updated along the way during key observation events. In the V2 project, the tag applied by the fresh produce supplier was read when it was staged for shipment and again when product was shipped out. The next observation occurred when the tag was read again, automatically with readers on the dock doors, once it arrived at the retailer's distribution center.

The technology isn't perfect yet, there are still some issues with reading product with high water content or metal packaging, but progress is made every day due to the efforts of universities, research labs and private companies alike. Government can help move the technology forward, by sponsoring research efforts that are taking place and staying involved and supporting the standards bodies that are working diligently to provide an infrastructure to track product through the supply chain.

RFID TAGS FOR TEMPERATURE MONITORING

Monitoring the "cool" supply chain with RFID temperature monitoring devices is another area where Franwell and the CFDR are actively engaged. Temperature is the characteristic of the distribution environment that has the greatest impact on the storage life and safety of fresh foods. Good temperature management is in fact, the most important, yet the simplest procedure for delaying product deterioration. Temperature is also the one factor that can be easily and promptly controlled. Preservation of fresh product quality and safety can only be achieved when the product is maintained under its optimum temperature as soon as possible after harvest or production. RFID can be combined with temperature monitoring devices to allow full visibility of a product's life cycle through the cold chain in real time. Although *E. coli* is not a result of poor temperature management, other health concerns are a direct result of temperature abuses. RFID temperature monitoring devices can be

used to ensure that product reaching the end-consumer has not suffered such abuses, resulting in safer product.

Temperature monitoring devices are widely used today, but the ones in use are not as robust or easy to use as the RFID monitoring devices that are available and being improved. The goal of RFID-enabled monitoring is to reduce the reading time of temperature devices, giving the receiver in a warehouse an initial accept/reject indication real-time, without delay. Current practices might deploy one or two monitoring devices per trailer load of product, those devices will tell you what the temperature has been in that area of the trailer, but will not tell you the temperature of the individual cases or even certain pallets of product and they must be retrieved and read manually.

Our vision includes the use of more devices, at the pallet level and eventually even the case level and applying these labels earlier in the process, back to the cooler at the shipper location. RFID devices also have the advantage of offering standard interpretation of data, rather than leaving the interpretation up to the receiving dock personnel. Also, the read can be automated, hopefully with the same readers that are being used for tracking product, providing more reads and enabling more consistent quality procedures overall. This automatically captured data could be used by software systems to provide a higher-level of business intelligence that will provide for further interpretation of all temperature fluctuations and the effect on product quality and safety.

Information technologies can be used in many ways to make the supply chain more efficient and safer. But for these systems to be effective, they have to be interoperable. And to be interoperable, we need industry-wide standards. Without such standards, one company's readers won't read another company's tags, and so on. For example, if we're going to have an effective RFID track-and-trace system to facilitate product recalls, it has to be uniform from one company to the next and in today's global economy, it has to be uniform from one country to the next. This is a tremendous challenge that is being taken on by industry standards groups, such as EPCglobal.

In some cases, industry has done a very good job in producing widely-accepted standards. In other cases, it's important for the Government to play a leadership role. It isn't easy and can be a long difficult process, but standardization is critical to widespread implementation of any new technology and those standards must stretch beyond company and country borders.

Congress and the Administration can help by encouraging the FDA and USDA to work with standards groups. Federal Government can also help by sponsoring research efforts, such as the work being done at the University of Florida and other universities and private technology companies focused on developing important new technologies. And finally, the Federal Government needs to reinforce to private industry the importance of cooperating on standards, and that track and trace of product and ensuring a safe food supply should never be a reactive afterthought.

Thank you again for the opportunity to testify today. I'd be happy to answer any questions you may have.

The CHAIRMAN. Thank you.

Mr. Palmer.

STATEMENT OF JEFF PALMER, PRESIDENT, DAYMARK SAFETY SYSTEMS, BOWLING GREEN, OH

Mr. PALMER. Mr. Chairman and distinguished members of the committee, I want to thank you for holding this hearing and giving us the opportunity to express our views regarding food safety.

I am Jeff Palmer, President of DayMark Safety Systems, a company well known for its expertise in providing solutions for safe and efficient food rotation. In fact, DayMark is the No. 1 provider of products and solutions for safety in food service and the restaurants today.

As you see in the appendix to our statement, we are one of four innovative companies belonging to the CMC Group, established 27 years ago in Bowling Green, Ohio. DayMark's mission is to provide efficient, economical and innovative ways to label food in compliance with Federal food codes as well as provide additional food

safety products, technologies, services and solutions for the food service industry.

We clearly advocate that proper labeling protects consumers from foodborne illness outbreaks. Proper labeling proactively supports first in, first out food rotation. Proper labeling with the HACCP system is a process that uses a combination of proper food handling procedures, monitoring techniques and recordkeeping to ensure food safety. Proper labeling reduces spoilage and food costs when products are dated correctly and staff becomes accountable for managing food storage and preparation.

Proper labeling reduces labor, time and costs. Proper labeling ensures product freshness and flavor. Proper labeling enables food service operators to become compliant with FDA regulations. The challenge for government is how to implement plans to prevent foodborne illness, including *E. coli*. Food rotation is critical when storing food products because improperly stored items can result in food spoilage, which in turn, requires additional purchases that can deplete a company's resources.

At DayMark, labeling technology is rapidly evolving. We have many new ideas at work to safeguard consumers. We've been the innovator in the labeling field since 1997 with the introduction of Dissolve-Away and Dissolve-Mark labels. These labels are used for dry and cool storage and are ideal for food rotation because each label contains space that includes the name of the product, used by date and expiration date. But unlike permanent adhesive labels, Dissolve-Mark labels dissolve in warm water in under 30 seconds and leave no sticky residue, which could harbor bacteria on storage containers.

Other innovations include Dissolve-Away tape, Chill-Check, Hot Hold labels, repositionable labels, daily week portion bags, disposable grip-to-go, pastry bags, protective gloves, OSHA-compliant first aid kits and freezable labels.

One of our food safety tools in today's discussion is the DayMark Timestrip food freshness indicator. Food service operators who are interested in an effective method for identifying the shelf life of perishable inventory can use DayMark Timestrip. The timestrip helps kitchen staff to use food products before they are no longer safe to serve. It's a visual alarm clock with a universal language.

In addition to innovation, DayMark brings awareness to the food service industry. Our employees are experts in food and personal safety and have been trained and certified to help food service professionals develop the best systems to fit their operational needs.

At DayMark, we continually assist food service owners, managers and employees with complete safety solutions.

In summation, clearly millions of foodborne illness and thousands of hospitalizations and foodborne illness disease-related deaths tell us that proper safety procedures, processes, training, education and tools are needed.

Finally, the use of products including food rotation labeling systems and Timestrip, provided by DayMark Safety Systems fully support our government and FDA efforts to safeguard consumers. Thank you.

[The prepared statement of Mr. Palmer follows:]

PREPARED STATEMENT OF JEFF S. PALMER

Mr. Chairman and distinguished members of the committee, I want to thank you for holding this hearing and giving us the opportunity to express our views regarding *Food Safety: Current Challenges and New Ideas to Safeguard Consumers*.

I am Jeff Palmer, President of DayMark® Safety Systems, a company well known for its expertise in providing solutions for safe and efficient food rotation. In fact, DayMark is the #1 provider of products and solutions for safety in the food service, or restaurant industry today.

As you can see in the appendix to our statement, we are one of four innovative companies belonging to the CMC Group, established 27 years ago in Bowling Green, Ohio. Our mission is to provide efficient, economical, and innovative ways to label foods in compliance with Federal Food Codes as well as to provide additional food safety products, services and solutions for the food service industry.

Primarily, DayMark Safety Systems specializes in products that assist food service establishments. Our products are used to provide efficient, economical, innovative ways to label foods in compliance with food safety standards.

We clearly advocate that proper labeling:

- Protects consumers from foodborne illness outbreaks.
- Proactively supports "first in, first out" (FIFO) food rotation.
- Supports operators that use the standard HACCP program. The HACCP system (Hazard Analysis Critical Control Points) is a process which uses a combination of proper food handling procedures, monitoring techniques, and recordkeeping to help ensure food safety. By instituting a HACCP system, food service managers can identify areas where contamination or growth of microorganisms can occur. Control procedures can then be implemented to contain the problem and prevent future occurrences. The use of a HACCP system is vital. The Centers for Disease Control and Prevention (CDC) estimate that there are between 76 million cases of foodborne illnesses each year in the United States. These instances result in an estimated 325,000 hospitalizations and 5,000 deaths. This number is staggering, especially when many of these illnesses could be prevented with the proper food rotation procedures.
- Reduces spoilage and food costs when products are dated correctly and staff becomes accountable for managing food storage and preparation.
- Reduces labor time and costs to properly label food products in commercial kitchens, which increases compliance.
- Ensures product freshness and flavor.
- Enables food service operators to become compliant with FDA regulations.

Furthermore, food operators using the FIFO method of food rotation and food operators following a HACCP program must use labels to comply with these methods.

The challenge for government is how to implement plans to prevent foodborne illnesses, including *E. coli*. According to the world health organization, it is estimated that up to 30 percent of all people in industrialized countries may be affected by foodborne illness. As I stated before, approximately 5,000 people a year die from foodborne illness in the United States alone. In addition, it is believed that some 1.7 million children worldwide aged 0–15 years die every year as a result of diarrhea caused by water or foodborne microorganisms. Most all of this sickness and death could be prevented with proper procedures.

Furthermore, food rotation is critical when storing food products because improperly stored items can result in food spoilage, which in turn, requires additional purchases that can deplete a company's resources. Because of this, the value of labeling in storing food products is critical. By properly labeling food, food service managers will save on food costs, reduce or eliminate cross contamination and foodborne illnesses and streamline employee communication across work shifts. Our bi-lingual and tri-lingual labels, for example, also remove language barriers.

At DayMark labeling technology is rapidly evolving. We have many new ideas that work to safeguard consumers. We have been an innovator in the labeling field since 1997 with the introduction of the Dissolve-A-Way® and DissolveMark™ labels. These labels, used for dry and cold storage, are ideal for food rotation because each label contains space to include the name of the product, use-by-date and expiration date. But, unlike permanent adhesive labels, DissolveMark™ labels dissolve in warm water in under 30 seconds and leave no sticky residue, which can harbor harmful bacteria on storage containers.

Other innovations include Dissolve-A-Way Tape, ChillCheck & HotHold Labels, Removeable Labels, Repositionable Labels, Freezable Labels, Day-of-the-Week Portion Bags, Disposable Grip2Go Pastry Bags, Protective gloves and OSHA compliant First Aid Kits.

One of our food safety tools most applicable to today's discussion is the DayMark Timestrip—food freshness indicator. Food service operators who are interested in an effective method for identifying the shelf life of their perishable inventory can use DayMark's Timestrip. The Timestrip helps kitchen staff identify and use food products before they are no longer safe to serve. It also improves monitoring to help meet HACCP regulatory standards.

In addition to innovation, DayMark brings awareness to the food service industry. Our employees are experts in food and personal safety and have been trained and certified to help food service professionals develop the best safety system to fit their operational needs. At DayMark, we continually assist food service owners, managers and employees with complete safety solutions.

Three simple rules have been DayMark's cornerstone since inception:

1. Take care of every customer by the golden rule: treat him or her the way we would want to be treated.

2. Handle every customer with the highest level of efficiency and effectiveness.

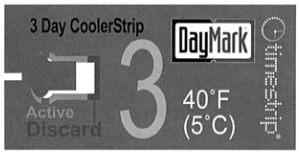
3. Lead the development of cutting edge technology and products that make the operator more cost-effective and compliant with current Federal food codes.

In summation, clearly the millions of foodborne illnesses and thousands of hospitalizations in foodborne disease-related deaths tell us proper safety procedures, processes, training, education, and tools are needed.

And finally, the use of products including food rotation labeling systems and Timestrip provided by DayMark Safety Systems fully suppport our government and FDA's efforts to safeguard consumers.

DayMark®
Safety Systems

timestrip®



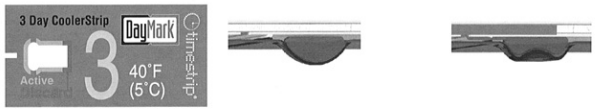
Innovative technology that monitors lapsed time for perishable food items.

 # 1 in Food Safety. Now in Personal Safety.

DayMark®
Safety Systems

timestrip®

Take It Click It Stick It



 # 1 in Food Safety. Now in Personal Safety.

DayMark® Safety Systems

timestrip®

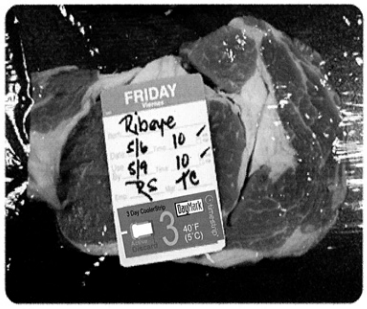
Before Activation | After Activation | Expired

 # 1 in Food Safety. Now in Personal Safety.

DayMark® Safety Systems

timestrip®

Turns Red to keep your food from turning Brown.



 # 1 in Food Safety. Now in Personal Safety.

DayMark® Safety Systems

timestrip®

Timestrip® used here to monitor freshness of chicken.

 # 1 in Food Safety. Now in Personal Safety.

DayMark® Safety Systems

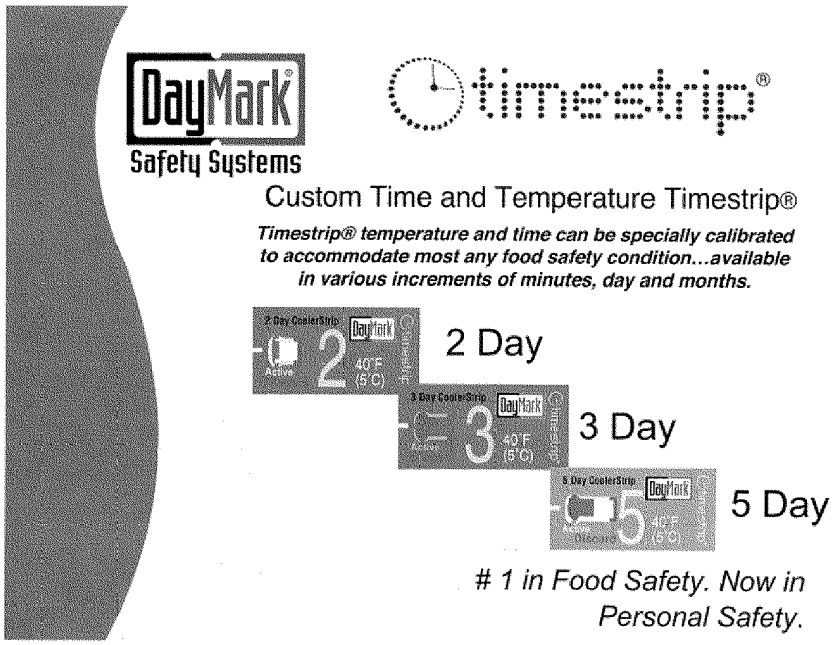
timestrip®

Perfect
for Fine Cheese

Excellent
for Steak & Choice Meats

Ideal
for Fish and Seafood

 # 1 in Food Safety. Now in Personal Safety.



The CHAIRMAN. Thank you. Great job summarizing.
Mr. Vazzana.

STATEMENT OF MR. JOHN VAZZANA, PRESIDENT AND CEO, INTRALYTIX, INC., BALTIMORE, MD

Mr. VAZZANA. I'd like to thank you, Mr. Chairman, Senator Burr and the rest of the committee for an opportunity to talk to you about our company and our technology.

Intralytix was founded in 1998 by a group of business and technical leaders in Baltimore, Maryland. Two of the founders were Dr. Torrey C. Brown and Dr. J. Glenn Morris. Dr. Brown is Chairman of the Board of Intralytix. He is the former Secretary of Natural Resources for the State of Maryland and a former Assistant Dean of the John Hopkins School of Medicine. Dr. Morris is Dean of the School of Public Health at the University of Maryland. He is one of the leading experts in infectious disease and a specialist in food safety. From 1994 to 1996, he was the Director of the Emergency Response Program at the Food Safety Inspection Services, U.S. Department of Agriculture and played a key role in the preparation of the 1995 USDA regulations on microbial safety in meat processing. These regulations are commonly known as HACCP.

Intralytix is a biologics company focused on the development of bacteriophage products for the food safety, animal health and human health markets. The emergence of antibiotic resistant bacteria has created a demand for new technologies to address health and safety problems existing in these markets. Bacteriophages or as we commonly call them, phages, are a class of viruses that occur abundantly in nature and attack a bacteria in a strain-specific

fashion. A phage effective against *E. coli* O157:H7 will have no effect on listeria. Phages are the most ubiquitous organisms on the earth today. One milliliter of unpolluted water contains 200 million phages. In the environment, phages and their bacterial targets have evolved over billions and billions of years. For every strain of bacteria, there is a phage that will kill it.

Phages do not interact with humans, animals or plant cells and for this reason, they have a highly favorable safety profile.

Phages were discovered in 1917 by Felix d'Herelle and in the 1930s, Elli Lilly had seven phage-based products on the market. With the advent of antibiotics, phage technology went out of favor in the west but since 1917 and to the present, phage therapy has been used widely in Eastern Europe. There has never been any serious adverse effect reported from phage therapy.

The company has developed products effective against listeria, salmonella and *E. coli*. In August 2006, FDA approved our product, LMP 102. LMP 102 is a phage product effective against listeria monocytogenes. Listeria monocytogenes infects about 2,500 people each year in the United States. Over 20 percent of these people die. This represents the first FDA approval of a phage product and provides a template for future phage-based food additive products.

ECP–100 is a phage product effective against *E. coli* 0571:H7. *E. coli* O157:H7 is a strain of *E. coli* that is commonly associated with contamination of hamburger. It is also the *E. coli* strain that was associated with the outbreak in spinach.

Intralytix anticipates filing a food addition petition with FDA in December ECP–100. Except for the target bacteria, our proposed regulation for ECP–100 will be identical to the regulation approved by FDA for LMP 102. Our attorneys estimate that it will take 18 months to obtain regulatory approval. We believe this to be excessive. We believe the Food Contact Notification Program should be expanded to include phage products. This would reduce the approval process to approximately 120 days.

SPLX–1 is a phage product effective against salmonella. Intralytix anticipates filing a food additive petition in June 2007. Today, a significant percentage of raw poultry sold to the consumer is contaminated with salmonella. Even though the salmonella is killed if the poultry is properly cooked, the secondary or cross contaminations are a major cause of salmonella poisoning. Again, we believe a mechanism should be adopted that would permit the approval of this product quickly.

Intralytix has also developed a phage product for chronic wounds. The product, WPP 201, targets Venus and diabetic ulcers. These chronic wounds quickly develop antibiotic resistant infections. The wounds also develop a biofilm that protects the bacteria. We believe phages can penetrate the biofilm and lyse the antibiotic resistant bacteria. FDA recently approved the first human trial. We appreciate the responsiveness of the Biologics Group at FDA in approving this human trial.

The use of phages in food safety and medical applications makes more effective a widespread, natural process that is already occurring on our environment, in our bodies and on our food. Each of you in this room hosts billions of phages in your body. The virtues of phage lie in their nearly unlimited ability to target existing and

new bacterial pathogens, the complete safety of their use and the ability to develop and deploy phage products to counter new bacterial strains quickly.

Thank you for this opportunity.

[The prepared statement of Mr. Vazzana follows:]

PREPARED STATEMENT OF JOHN VAZZANA

INTRODUCTION

Intralytix, Inc is a biologics company focused on the development of bacteriophage-based products for the food safety, animal health, and human health markets. The emergence of antibiotic resistant bacteria has created a demand for new technologies to address health and safety problems existing in these markets.

Bacteriophages (phages) are a class of viruses that occur abundantly in nature and attack bacteria in a species-specific or strain-specific fashion. The use of phages in food safety and medical applications harnesses and makes more effective a widespread natural process that is already occurring in our environment, within our bodies, and on our food as we speak. The virtues of phage lie in their nearly unlimited ability to target existing and new bacterial pathogens, the complete safety of their use, and the ability to develop and deploy phage to counter new bacterial threats within a few months of detection.

Phages are the most-numerous life form on earth; some estimates place the phage population in the range of between 10^{31} and 10^{32}. In the environment, phages have evolved in parallel with their bacterial targets. They are robust entities that keep in check their bacterial-population counterparts and play an important role in the balance of all ecosystems.

Phages interact neither with humans, animals nor with plant cells, and therefore have a highly favorable safety profile. Phages have been used for several decades in Eastern Europe, and are effective in a number of situations where antibiotics are inadequate due either to bacterial resistance or poor blood supply; such situations include osteomyelitis, diabetic ulcers and severe burns.

"Simply stated, phages are viruses that infect bacteria. Like all viruses, phages are metabolically inert in their extracellular form and reproduce by insinuating themselves into the metabolism of the host bacteria. The viral DNA is then injected into the host cell, where it directs the production of progeny phages. These phages burst from the host cell, killing it and then infecting more bacteria. There are innumerable types of phages, each capable of eradicating its host bacterial species. They are abundant in the biosphere and can be produced on a large scale, very economically. It is important to note that phages only attack bacteria and have absolutely no adverse effect on humans, animals or the environment." *Company's Website www.intralytic.com*.

Phages were also used in the United States and Europe during the early 20th Century. In the 1920s, Eli Lilly had at least seven phage products on the market. However, phages fell into disuse with the advent of broad-spectrum antibiotics. This was due to at least four reasons:

- Broad-spectrum antibiotics were easier to use than were phages, each of which have focused, narrow-spectrum activity.
- The medical crisis in wound treatment created by World War II, accelerating the demand for broad-spectrum antibiotics.
- Consistency, quality control and purity of phages (and phage therapy) were not always maintained.
- There was not broad consensus as to what phages were; two prevailing views had phages as either (1) viruses or (2) enzymes. For many, the actual nature of phages was settled only with the advent of electron microscopy, when the first images of phages (as virus particles) were finally obtained.

With the increasing threats from antibiotic resistant infections, phage research and development has increased sharply. Intralytix has developed products that address antibiotic resistant infections in wounds.

While phages were largely abandoned in the West, they continued to play an important role in the Soviet Union, where Giorgi Eliava established a research institute in Tbilisi, Georgia (Republic of Georgia) in collaboration with Felix d'Herelle, co-discoverer and prolific explorer of phages. That institute, now called the Eliava Institute, became the center for research and development of phage therapy.

Today, phage capabilities are still being developed in the former Soviet Union, particularly at the Eliava Institute in Georgia. Phages are also being explored by several U.S. and European firms, but no phages have yet to enter FDA-approved

human trials. A couple of firms are pursuing veterinary or agricultural applications in the United States and/or Canada. It is a principal objective of Intralytix to be the first company with phages in FDA-approved human trials.

Given the media attention to emergent infections and bioterrorism, it is not surprising that there has been significant mass-media coverage of phage therapy over the past couple years. Recent mention of the clinical potential of phages includes (but is not limited to):

1. Print media
   a. Science
   b. Wired—October 2003
   c. International Journal of Dermatology
   d. LA Times and NY Times
   e. Book: *The Killers Within*—has a chapter on phage therapy
   f. Recent story (9 December 2003) in the Star-Ledger newspaper in New Jersey
2. Other media
   a. Television programs
      i. Fox 5 Morning news
      ii. CBS News
      iii. BBC: The Virus that Cures
      iv. 48 Hours
      v. Canadian Discover program
      vi. Dateline Australia
      vii. The Nature of Things
   b. A Canadian/French joint documentary film currently being made on phage therapy. "Before penicillin became the medical world's darling, crusading doctors crisscrossed the globe armed with bacteriophages, bacteria killing viruses that, when administered to diseased patients via injection or potion, could be powerful healers" *U.S. News and World Report; Return of a killer—Phages may once again fight tough bacterial infections; November 2, 1998*.

INTRALYTIX

Intralytix was founded in 1998 by a group of business and technology leaders in Baltimore, Maryland. Today the founders make up the majority of the Board of Directors. A brief resumé of each Board member is attached. The initial funding of the Company was provided by development partners interested in the development of products that would make their products safer. As a result of a development contract with Perdue Farms, the Company was able to develop products effective against *Listeria and Salmonella*. Agreements with Alpharma have resulted in the development of animal health products effective against *Salmonella* and *Clostridium perfringens*.

FOUNDERS

Dr. Torrey C. Brown, M.D. is the Chairman of the Board of Intralytix. Dr. Brown is the former State of Maryland Secretary of Natural Resources and is the former CEO and current chair of Family Health International. During Dr. Brown's tenure Family Health International grew from $9 M to $100M in annual revenues. He is a former Assistant Dean of the Johns Hopkins Medical School and member of the Maryland State Legislature, having served for 12 years.

Dr. J. Glenn Morris, Jr., M.D. is currently the Chairman of the Department of Epidemiology and Preventive Medicine at the University of Maryland Medical School, as well as Professor of Medicine and Professor of Microbiology and Immunology. He is an experienced infectious disease physician, epidemiologist, and specialist in food safety. From 1994–1996 he was Director of the Epidemiology and Emergency Response Program at the Food Safety Inspection Service, USDA, and played a key role in the preparation of the 1995 USDA regulations on microbial safety in meat processing (the HACCP rule).

Dr. Sulakvelidze, a co-founder of Intralytix, received his formal training in microbiology in the former Soviet Union, including a B.A. from Tbilisi State University, a Ph.D. from Tbilisi State Medical University, and specialized training at the Engelhard Institute of Molecular Biology, Russian Academy of Sciences, Moscow, Russia, and the University of Maryland School of Medicine, Baltimore, Maryland, USA.

Dr. Sulakvelidze's research interests are in the broad areas of emerging infectious diseases, molecular epidemiology, pathogenesis of diseases caused by bacterial enteric pathogens, bacterial toxins, and phage therapy. One of the major focuses in Dr. Sulakvelidze's research are studies of the potential usefulness of bacteriophages

in preventing and treating infectious diseases caused by multidrug-resistant bacteria. The ability of lytic phages to reduce/eliminate colonization with, and treat diseases caused by, vancomycin-resistant enterococci, imipenem-resistant *Pseudomonas aeruginosa*, various *Salmonella* serotypes, and other bacterial pathogens have been studied. Dr. Sulakvelidze is also actively involved, in close collaboration with the Maryland Department of Health and Mental Hygiene, with studies of emerging infectious diseases. These studies include molecular epidemiological characterization of selected pathogenic strains by modern molecular typing techniques (PFGE, AP-PCR, etc.) and active participation in Maryland's Emerging Infectious Diseases Program (EIP) sponsored by the CDC.

Gary Pasternack, M.D., Ph.D., a co-founder of Intralytix, is a pathologist with extensive experience as a principal and a consultant in biotechnology businesses. Formerly he was the Director of the Division of Molecular Pathology at the Johns Hopkins University School of Medicine. Dr. Pasternack has served as member or chair of numerous review panels for the National Institutes of Health and the U.S. Army Medical Research and Materiel Command; he currently serves on a panel reviewing SBIR applications for the National Cancer Institute.

Patrick Hervy, a co-founder of Intralytix, is an experienced businessman who holds an MBA from Wharton. He is the founder, Chairman, and CEO of XLHealth Corporation. He is a member of the Board of Directors of Paragon Biotech, Inc. and has served as the former Chairman of MdBio, Inc. He is the former Chief Executive Officer of U.S. operations for Thomsen CGR.

John Woloszyn, JD, has been a business attorney with over 25 years experience representing technology-based companies. Mr. Woloszyn is a corporate attorney for multiple biotech, medical device, information technologies, and Internet companies. He has extensive experience in mergers, acquisitions, capital formation and the development of emerging growth companies. He is a member of the Board of Directors of MdBio, Inc., Chairman of the Board of Directors for Lombard Securities, Inc. and Chairman of Primaryimmune Services, Inc. He was a former Co-Vice Chair of Greater Baltimore Technology Council and member of the board of the NASA/Goddard Emerging Technologies Center in Baltimore, Maryland.

Nina Siegler, CFA, a co-founder of Intralytix, is an expert in licensing and technology transfer. Ms. Siegler is a former Wall Street biotech analyst who later went on to found the technology transfer office at the National Institutes of Health. Ms. Siegler is the former head of technology transfer for the Johns Hopkins University at Homewood.

EXISTING PRODUCTS

As a result of the strategic alliance with Perdue Farms, the company has developed products effective against *Listeria and Salmonella*. The products can be used as food safety and animal health products. The *Listeria* product, LMP 102, has been approved by FDA as a food additive.

The FDA approval gives us a template for future food additive products. We intend to submit a petition to FDA before the end of 2006 for an *E-coli* O157:H7 food safety product. The product can be used on both red meat, and fruits and vegetables such as lettuce and spinach. Our proposed regulation will be identical to the regulation approved for LMP 102. We would hope this would help expedite the approval process.

Intralytix will submit a food additive petition to FDA in the second quarter of 2007 for prevention of *Salmonella* in poultry and eggs.

As a result of our research with *Salmonella*, we have developed a *Salmonella* vaccine that has proven to be very effective in reducing *Salmonella* colonization in poultry. When administered to newborn chickens, it reduces *Salmonella* colonization. In a study conducted by Perdue, Perdue reported that the Company's vaccine not only reduces colonization, but also improves the feed conversion ratio of the flock.

During the development of our *Salmonella* vaccine, we discovered that vaccines created using the company's phage-based technology appear to have better immunogenicity than vaccines created with standard technology. We believe this is an important technology platform for future products, initially in the field of animal health, but eventually for human health.

We currently have environmental products effective against *Salmonella* and *Listeria*. We have submitted our *Listeria* product to EPA for their approval. We believe the product has a market in food processing facilities.

PhagoBioDerm is a novel bandage-like wound-healing preparation consisting of a biodegradable polymer impregnated with antibiotic and bacteriophages that was recently licensed for sale in the Republic of Georgia (one of the former Soviet Union republics). PhagoBioDerm is the trade name for a 0.2-mm-thick, perforated wound

dressing prepared as 4 x 5 cm films having a white/light yellow color. The films are impregnated with a mixture of lytic bacteriophages, an antibiotic, an analgesic, and sodium hydrocarbonate. The phage preparation is available commercially in the Republic of Georgia, and includes lytic bacteriophages active against *Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus, Streptococcus,* and *Proteus*.

TECHNOLOGY

Bacteriophages, the natural predators of bacteria, were one of the first specific antibacterial therapies to become available. In the earlier part of this century, bacteriophage therapy was commonplace. Eli Lilly & Co. listed several phage products until the early 1940's. Because of variability due to the then-incomplete understanding of phage biology, and because the immediate need of the medical community was for broad-spectrum antibacterials, bacteriophage therapy fell out of favor in the West. Eastern European and Soviet scientists, however, continued to develop bacteriophage technology alongside antibiotics, recognizing the inherent safety of bacteriophages and their complementarities to antibiotics.

Bacteriophages are viruses that infect bacteria but cannot infect human or animal cells. At approximately 1/75,000th of an inch, bacteriophages are much smaller than their bacterial foes. The structure of a bacteriophage is similar to a lunar lander, with a hollow head packed with bacteriophage genes, a tunnel-like tail, and long spindly legs. Once the phage lands upon its prey, the core of its tail creates a channel communicating with the interior of the bacterial cell. The bacteriophage uses the channel to inject its own genes inside the bacterial prey. Once injected, the phage genes commandeer the host machinery and force it to construct new phages, as many as 200 within three-quarters of an hour. Eventually, the overproduction of phages bursts and destroys the bacterium, sending the newly minted phages forth to infect more bacteria. Several key differences render animal cells impervious to phage: (1) the receptors, or chemical signals to which phage initially bind are found on bacterial surfaces but not the surfaces of animal cells; (2) phage are adapted to inject genes through the cell wall of bacteria, not the completely different membranes of animal cells; and (3) phage can take over the cellular machinery of bacteria, but not the completely different machinery of animal cells.

Resurgent interest in phage technology in the West is largely due to the emergence of antibiotic-resistant organisms. The lay press is filled with reports of so-called super bugs that are resistant to all known antibiotics, including those of last resort. In the United States, numerous hospitalized patients die each year because there is no effective antibiotic to treat their vancomycin-resistant *Enterococci*, or methicillin-resistant *Staphylococci*. Yet these same strains are sensitive to bacteriophages.

Phage therapy has great appeal. Data from Eastern Europe and the former Soviet Union indicate that bacteriophages are not only effective, but they are safe as well. Bacteriophages trigger no allergic reaction in humans. In fact, phages are extremely common in the environment, are regularly consumed in foods, and are found as unintended contaminants in a variety of medications, including commercially available vaccines widely used in the United States. For example, there may be as many as 200,000,000 phages per milliliter of unpolluted water. There are virtually no reports of complications, environmental or clinical, associated with the use of therapeutic phages. Bacteriophages thus appear to be safe for many applications including food processing and sanitation as well as for direct therapeutic applications in humans.

Commercial use of bacteriophages occurred in the West in the 1930's and early 1940's as previously mentioned. Phages were listed and sold as biological therapies by Eli Lilly, E.R. Squibb and Sons, and Swan-Myers (Abbot Laboratories). These products were used in mixed infections of the soft tissues, infected surgical wounds of the abdomen and pelvis, and in nonspecific genito-urinary infections. The Pasteur Institute in Paris prepared and used phages on a case-by-case basis. In the East, the Ministry of Health of the former Soviet Union routinely licensed active phage preparations for use in humans for treatment of wound, enteric, and respiratory infections.

Environmental effects are extremely unlikely since bacteriophages are ubiquitous. Commercial development involves selection of the appropriate naturally occurring phages that specifically, selectively, and efficiently kill the desired bacteria. No phages selected for use in food processing, sanitation, or therapy are capable of so-called lysogeny, where phages of undesirable classes insert into and alter bacterial DNA. Lytic phages, the type exclusively used by Intralytix, destroy their bacterial hosts without the possibility of transferring DNA. In order to ensure the phages used are lytic, Intralytix sequences all of our phages, and look for any undesirable genes. Since the bacteriophages cannot proliferate in the absence of their specific

host, they disappear and become undetectable shortly after the last bacterium is killed. Bacteriophages thus represent a self-cleaning modality that fades away after doing its work.

Bacteriophages were discovered by Twort and D'Herelle in the early part of this century. Because of their remarkable antimicrobial activity, phages were utilized for treating human infections almost immediately after their discovery, and they continued to be used therapeutically in the pre-antibiotic era worldwide. D'Herelle's commercial laboratory in Paris produced at least five phage preparations against various bacterial infections. In the United States, a large U.S. pharmaceutical company produced seven phage products for human use in the 1940s, including preparations targeted against staphylococci, streptococci, *E. coli*, and other bacterial pathogens. These preparations were used to treat various infections, including abscesses, suppurating wounds, vaginitis, acute and chronic infections of the upper respiratory tract, and mastoid infections. However, with the advent of antibiotics, interest in phage therapy waned in the United States and Western Europe. Antibiotics offered the broad bactericidal coverage necessary to treat infections prior to the establishment of a definitive diagnosis, whereas bacteriophages were exquisitely specific for individual bacterial strains or species. As a result, virtually no subsequent research was done on the potential therapeutic applications of phages in either humans or animals in the West. However, phages continued to be used therapeutically—together with, or instead of, antibiotics—in Eastern Europe and in the former Soviet Union. Several institutions in these countries were actively involved in therapeutic phage research and production, with activities centered at the Eliava Institute of Bacteriophage, Microbiology, and Virology of the Georgian Academy of Sciences, Tbilisi, Georgia,

Intralytix is a pioneer U.S. company working on therapeutic bacteriophages. The company has made a significant progress in bringing phage technology to the cutting-edge biotech level by (a) identifying novel, commercially important applications for phage technology, (b) utilizing expertise from eastern European and former Soviet Union countries to adapt and improve state-of-the-art phage technology, (c) applying modern scientific approaches to better understand phage biology and phage-bacterial cell interactions, and (d) utilizing modern, state-of-the-art, biological processing technology. To this end, Intralytix has achieved a number of significant milestones, and it possesses significant expertise in the field that positions it well ahead of the competition. For example, Intralytix has:

(i) optimized phage isolation and propagation techniques, which enabled the company to construct a large library of monophages against various multi-drug-resistant bacterial pathogens,

(ii) developed pertinent animal models for evaluating phage safety and efficacy,

(iii) delineated optimal phage delivery routes and dosage levels for environmental decontamination and clinical applications,

(iv) optimized purification procedures for obtaining highly purified and concentrated phage preparations, and

(v) determined optimal conditions for freeze-drying phages, which result in water-dispensable, easily transportable, and stable viable phage preparations.

Phages are "natural products," that are ubiquitous in the environment. For example, 1 ml of non-polluted water contains approximately 200,000,000 phages. Because of this, the environment is an excellent source for lytic phages; majority of Intralytix's phages, for example, were isolated from the waters of Baltimore Inner Harbor or Chesapeake Bay. Technologically, initial isolation of phages is a relatively straightforward procedure, and is an exercise often included in advanced college microbiology course laboratories. However, only a small fraction of all isolated phages will prove to have utility as a therapeutic agent. Identification of phages having broad lytic activity against a specific pathogen is a complex process, involving repeated isolation, propagation, and characterization of phages over a period of time. As noted above, Intralytix has proprietary technology for efficient phage isolation, identification, characterization, propagation, and purification. The company has used this technology to develop an extensive library of monophages targeted against various specific pathogens. This technology (and the resultant phage library) is one of the key elements in the ability of the company to rapidly move forward with commercialization of phage products.

For production, phages are produced in fermenter lots by growing them on their host bacteria. Subsequent separation and purification of phages, and removal of adventitious material, involves *know how* technology proprietary to the company. At that point, as per an Intralytix-developed procedure, various phage preparations are constructed by mixing several separately grown and well-characterized lytic monophages, in order to: (a) achieve the desired, broad target activity of the phage

preparation, (b) ensure that the preparation has stable lytic properties, and (c) minimize the development of resistance against the preparation. Phages and phage preparations can be stored as concentrated liquid preparations (stable for at least 6 months), or can be freeze-dried (viable indefinitely long).

In studies conducted by Intralytix, the Company's phages were highly effective in decontamination of environmental surfaces and electronic equipment. In studies conducted in collaboration with investigators at the Agricultural Research Service, USDA, aerosolized phage preparations have also been highly effective in reducing pathogens on various fruits and vegetables by several logs (from 100 to over 1,000 fold). Thus, phages are proven to be highly effective in these settings. However, appropriate technology for phage delivery and optimal application methodologies must be developed for phage treatment to be maximally effective. *Intralytix has developed such technology*.

LMP 102

Identity and Formulation

LMP 102 is a phage preparation consisting of a mixture of equal proportions of six individually purified phage, each of which is specifically effective against genetically diverse *Listeria monocytogenes* strain populations. It is possible to optimize the effectiveness of the preparation by customizing for differences in *L. monocytogenes* strains and serotypes that predominate in different geographic regions of the country or that may be associated with particular food type facilities. Six different phages will always be used to provide robustness.

Bacteriophages have been isolated from drinking water and from a wide range of food products, including ground beef, pork sausage, chicken, farmed freshwater fish, common carp and marine fish, oil sardine, raw skim milk, and cheese.

LMP-102 is all natural product that contains six bacteriophages isolated from the environment. The phages have not been altered or manipulated in any way. The preparation is specifically targeted against *L. monocytogenes*—one of the deadliest foodborne bacteria that kill approximately 25 percent of the people infected. The product does not otherwise alter the general composition of the foods, and it triggers no adverse organoleptic changes (i.e., it does not alter taste, odor or color of treated foods). The product has no effect on food shelf life (i.e., it does not extend the shelf life of treated foods).

The product is all natural, and no media of animal origin has been used during its preparation. In addition, no known, potentially allergenic substances (wheat, milk, soy, etc.) have been added to/mixed with the product.

The phage component of LMP-102™ is roughly estimated to be 0.1 ppm by weight and the remainder is phosphate-buffered saline containing up to 125 ppm residual organics from the growth medium and biomass.

The LMP-102™ article of commerce is a liquid made up of six monophages that individually have a lytic titer of 9.0 ± 0.5 $\log_{10}$ plaque-forming units (PFU) per ml.

LMP-102™ Proposed Use Levels

It is proposed that LMP-102™ be allowed for use as an antimicrobial processing aid in the production of ready-to-eat (RTE) meat and poultry products. LMP-102™ article of commerce is applied to the surface of the RTE food articles just prior to packaging. For most RTE food articles, this will require application of LMP-102™ at a rate of approximately 1 ml per 500 cm^2 (~2 $\mu l/cm^2$) of RTE food article surface area.

Directions for Use

Dispensing

Automated dispensing equipment will be used in most applications of LMP-102™. The dispensing equipment will be microprocessor controlled and will provide for accurate delivery of the phage solution to the specific application points. Dispensing equipment and commercial product package will have an integral "lock and key" connection device to prevent inadvertent dispensing of improper compositions. Dispensing system and package design will provide for near-complete evacuation of commercial product package to prevent excess discharge of active material to environment and waste stream.

Dispensing system will have an integrated clean-in-place (CIP) system to provide daily, or as required, cleaning and sanitizing of the dispensing system.

Application

The application mechanics may be different for each type of RTE food article treated with LMP-102™ solution. In all applications, the phage solution will be

spray applied onto the RTE food article surface. Low volume (low flow rate), low-pressure spray nozzles will be utilized to accurately dose the phages to all surfaces of the RTE food article. In some cases air-assisted spray nozzles may be employed to provide additional motive force to the low volume spray.

Description of Intended Technical Efect

LMP-102™ is intended to produce significant reduction of *L. monocytogenes* contamination vs. a water control when applied as directed to ready-to-eat (RTE) food products. LMP-102™ is further intended to produce significant reduction of *L. monocytogenes* contamination vs. an untreated control when applied as directed to RTE food products. In general, the reduction of *L. monocytogenes* contamination is better than 90 percent and often better than 99 percent."

Categories of Ready-to-Eat Food Products

LMP-102™ is intended to reduce *L. monocytogenes* contamination on a broad spectrum of RTE food products. RTE food products are products designed and labeled for consumption by the consumer without cooking at temperatures sufficient to kill any microbial contaminants that might be present. The following table represents categories of RTE meat and poultry products along with representative items in each category. The rationale behind the efficacy studies described in this section is that successful production of the intended technical effect on a foodstuff in a given category is indicative of efficacy among members of that category in general.

Categories of ready-to-eat food products

	Food category	Example
1	Cooked cured comminuted products, red meat	Beef frankfurters
2	Sliced cooked cured whole muscle cuts, red meat	Corned beef
3	Injected whole cooked muscle cuts, red meat	Flavored roast beef, uncured, water added
4	Sliced cooked whole muscle cuts, uninjected, red meat.	Roast beef, minimally processed
5	Cooked cured comminuted products, poultry	Turkey frankfurters
6	Sliced cooked cured whole muscle cuts, poultry	Turkey pastrami
7	Injected whole cooked muscle cuts, poultry	Roast turkey skin, uncured
8	Sliced cooked whole muscle cuts, poultry	Roast turkey, minimally processed
9	Sliced cooked comminuted meat products	Sliced bologna, beef & pork
10	Sliced cooked comminuted poultry products	Sliced bologna, turkey
11	Uncured fermented comminuted red meat products	Lebanon bologna
12	Uncured fermented comminuted poultry	Uncured turkey salami

Summary of Efficacy Data

Description of Test System

Efficacy studies were carried out under good laboratory practices (GLP). Twenty-seven samples of each of the 12 RTE products were inoculated on one surface with approximately 2 x 10^3 CFU per cm^2 of a 1:1:1 mixture of three *L. monocytogenes* strains, *L. monocytogenes* ATCC 19115 (serogroup 4b), *L. monocytogenes* Lm 68 (serogroup 1/2b), and *L. monocytogenes* Lm 82 (serogroup 1/2a). Samples were incubated for 20 ± 1 min at room temperature to allow for bacterial attachment. Nine samples of each inoculated RTE product were treated with LMP-102™. Nine samples of each inoculated RTE product were treated with a water control. The LMP-102™ and water control were applied to RTE product samples in a spray, using an airbrush adjusted to deliver 100 ± 20 µl per 4 seconds. All RTE product samples except frankfurters were sprayed for four seconds. Frankfurters were sprayed for a time period dependent upon their surface areas.

Following treatment, samples were vacuum packed and stored at 5 ± 2° C for 24 ± 4 h, 72 ± 4 h, or 168 ± 4 h. Samples were then analyzed for populations of *L. monocytogenes*. Phosphate buffered dilution water (PBDW, 100 ml) was added to the packages containing the RTE product samples, which were subsequently stomached. The resulting stomachates were serially diluted in PBDW and plated on MOX. Petri plates were incubated at 37 ± 2° C for 48 ± 4 h. The GLP Efficacy Study Report is included in Appendix F01.

Summary of Results

Compared with 250 ppm synthetic hard water only, LMP-102™ applied at a rate of approximately 1 ml per 500 cm^2 (~2 µl/cm^2), reduced populations of *L. monocytogenes* by 1.0-2.75 logs on all RTE products evaluated at 24 ± 4, 72 ± 4, and

168 ± 4 hours of storage at 5 ± 2° C. The reduction was statistically significant ($P < 0.05$). One exception was Lebanon bologna. Because Lebanon bologna exhibited intrinsic bactericidal activity against *L. monocytogenes*, recoverable populations in both treated and control samples were not obtainable in several instances, which resulted in a lack of variance in data. Thus, while application of LMP-102 appeared to reduce the levels of *L. monocytogenes* on Lebanon Bologna, statistical analysis was not possible in samples stored for 72 ± 4 and 168 ± 4 hours.

RTE product	Log_{10} reduction LMP-102™ treatment vs. water control		
	24 h	72 h	68 h
Beef frankfurters	1.91	1.45	1.25
Sliced ham	2.07	2.16	1.16
Flavored roast beef, uncured, water added	1.51	1.79	2.00
Roast beef, minimally processed	1.62	1.79	1.35
Turkey frankfurters	1.71	1.18	1.28
Turkey pastrami	1.48	1.88	1.83
Roast turkey skin, uncured	2.11	2.53	2.61
Roast turkey, minimally processed	1.49	1.36	1.33
Sliced bologna, beef & pork	2.34	2.69	2.45
Sliced bologna, turkey	2.67	2.57	2.75
Lebanon bologna	0.62	1.00	1.00
Uncured turkey salami	1.99	1.97	1.90

Safety of LMP-102™ Components

Safety of the Phages—Background Exposure to Phages and Phage Ubiquity

The safety and ubiquity of bacteriophages have been well established. The pertinent safety data on bacteriophages is briefly reviewed below. The published literature on phages, and other information developed by Intralytix, shows that:

• Bacteriophages are arguably the most ubiquitous organisms on earth. For example, one milliliter of non-polluted stream water has been reported Bergh et al., 1989 to contain approximately 2 x 10^8 PFU of phages/ml (Appendix H01), and the total number of phages on this planet has been estimated to be in the range of 10^{30}–10^{32}. This abundance of phages in the environment, and the continuous exposure of humans to them, explains the extremely good tolerance of the human organism to phages.

• Phages have been used therapeutically in humans for more than 80 years, without any recorded illness or death. During the long history of using phages as therapeutic agents in Eastern Europe and the former Soviet Union (and, before the antibiotic era, in the United States, France, Australia, and other countries), phages have been administered to humans (i) orally, in tablet or liquid formulations, (ii) rectally, (iii) locally (skin, eye, ear, nasal mucosa, etc.), in tampons, rinses and creams, (iv) as aerosols or intrapleural injections, and (v) intravenously, albeit to a lesser extent than (i) to (iv)—and there have been virtually no reports of serious complications associated with their use.

• Phages have also been administered to humans for non-therapeutic purposes without any recorded illness or death. To give just a few examples, phage preparations have been used extensively to monitor humoral immune function in humans in the United States in the 1970s–1990s, including in patients with Down's syndrome, the Wiskott-Aldrich syndrome and immunodeficient patients (Lopez et al., 1975; Ochs et al., 1982; Ochs et al., 1992; Ochs et al., 1993a). In some of the studies (including FDA-performed studies), the purified phages were injected intravenously into HIV-infected patients or other immunodeficient individuals without any apparent side effects (Fogelman et al., 2000; Ochs et al., 1971; Ochs et al., 1993b).

• The biology of phages has been exhaustively studied. These studies have clearly shown that phages are obligate intracellular parasites of bacteria and are not infectious in humans or other mammals.

• Phages have been found in commercial sera and in FDA-approved vaccines commercially available in the United States (Merril et al., 1972; Milch and Fornosi, 1975; Moody et al., 1975).

• Bacteriophages are common commensals of the human gut, and they are likely to play an important role in regulating the diversity and population structure of various bacteria in human GI tracts. Phages capable of infecting *E. coli, Bacteroides fragilis* and various *Salmonella* serotypes have been isolated from human fecal

specimens in concentrations as high as 10^5 PFU/100 g of feces (Calci et al., 1998; Furuse et al., 1983; Armon et al., 1997). The recent data based on metagenomic analyses (using partial shotgun sequencing) of an uncultured viral community from human feces suggested that bacteriophages are the second most abundant category after bacteria in the uncultured fecal library (Breitbart et al., 2003).

• No adverse immunologic or allergic sequelae have ever been reported because of human or animal exposure to phages.

The CHAIRMAN. Thank you very much. Dr. Whitaker, I'm impressed that there are six million bags of fresh salad a day consumed in the United States. I had no idea.

What do you think was the estimated cost to the spinach industry of this industry-wide recall, and do you have any suggestions for limiting the impact to the industry and reducing that number in a similar situation?

Dr. WHITAKER. I think the quantification of that is still ongoing but I understand—the number I've heard is about $100 million, across the whole industry.

The CHAIRMAN. OK. Do you have any suggestions for ways to limit the impact on an industry? We run into this with beef, too, when something happens anywhere in the country, people stop eating beef for a while and there are some pretty significant costs to our ranchers. So one of the things they've asked for is some additional confirmation before it becomes widely broadcast, but yet we want to make sure that we're notifying people so they have as little problem as possible.

Dr. WHITAKER. Yes, Mr. Chairman, it's paramount that when something like this happens that public safety be protected. Off the top of my mind, the thing that would help in the future is to be able to narrow it down sooner. We just heard officials talk about having it narrowed down to one process or 1 day within 2 weeks and yet, spinach itself was not—did not enter the marketplace again for another several weeks after that and even today, we still suffer from it because it was not broadcast clearly that this was limited to a single processor, single set of farms, on a single day. So I think, in that fashion, a little bit more timely notification probably would have helped us some. But when you have an outbreak like this, I mean, certainly the balance has to shift toward protecting the public health.

The CHAIRMAN. Thank you. Ms. Crawford, I'm interested in these tags because we've been, of course, talking about the country of origin labeling for cattle for some time and we've run into some real cost difficulties on that. So now we're talking about tagging each bag of produce. What do these labels, these RFIDs cost?

Ms. CRAWFORD. Well, actually in today's testimony, I didn't talk about tagging the individual units that you sell because the cost is still a little bit high for item level tagging and the read rates aren't really there for item level tagging. But for case level, I talked about tagging each case. So that's not nearly as impactful as tagging each bag and to be able to track product through the supply chain, just to know where it is, really at the case level, gives you a lot greater visibility than what you have today. So once that case is open and placed on the grocery shelf, if there is a recall, then the grocery personnel can go and look for that product on the grocery shelf but to be able to find all that product everywhere in the supply chain, if it was just on the cases, then to me, that's something that—the

technology is more readily available for, ready to react in that environment, the read rates are better at that level than they are at the each level. Of course, everyone in the industry wants to get to where RFID tags are at the each level. But the price has to come down and the performance has to go up and significant changes are made every day in both of those areas. So you can tag a case for—it all depends on the quantity of tags that you're buying, but you could probably tag a case for 20 cents. That's pretty inexpensive for public safety.

The CHAIRMAN. Is there a distance range to the transmission?

Ms. CRAWFORD. Yes, there is. Usually from 3 to 15 feet is what you're going to get from the type of tags that I'm talking about using.

The CHAIRMAN. Another concern I'm sure that we'll run into is, is the radio transmission dangerous to people or other products or technology? Will it affect people's health?

Ms. CRAWFORD. No. It's not dangerous. The paths of RFID tag is not dangerous to people and actually it's funny. Someone asked me that question recently and they said—it isn't funny though—"when people ask you that question, they're usually on their cell phone with that right up against their head." So they should be a little more concerned about that than about the frequency from the radio frequency ID tags.

The CHAIRMAN. Thank you. Mr. Palmer, how does your product differ from the time stamp that is on a package? The purchase by or sell no later than stamp?

Mr. PALMER. Well, currently the systems we sell are primarily in operations within restaurants and kitchens. So we would then help the operations in the back of a kitchen or restaurant properly rotate their food within the shelf life that is required. We do that through a dissolving label that would be put on a food container that would track the time it was prepared and the time it needs to be expired, meaning the shelf life of the food. If you wanted more extensive tracking of that within the food service operations, you could go to Timestrip, which tracks time and temperature.

The CHAIRMAN. Do they change color as the time goes by?

Mr. PALMER. On the Timestrip technology, yes it does. It turns red and it actually has a duration. It can be as low as 30 minutes and as long as 5 days. A red line will appear and it's capillary infusion technology that basically is a very eloquent technology but very simple at the same time because it's a universal language that basically says either this product is good to be used or it will be discarded. If the red line is all the way across the tag, it means to discard.

The CHAIRMAN. I'm also impressed by labels that will dissolve in 30 seconds. I had never thought about the need for freezable labels. I guess a lot of us don't work with that sort of thing.

As a small businessman, in developing your technology, did you have an opportunity to work with the Small Business Innovative Research grants, SBIR?

Mr. PALMER. We actually did work with Timestrip and the State of Ohio in doing that. Unfortunately, we weren't successful.

The CHAIRMAN. OK. Can you tell me a little bit more about how your technologies and products tie in with the hazard analysis and critical control points or HACCP procedures?

Mr. PALMER. Certainly. Since HACCP, OSHA and FDA regulations are in place, all driven by the need to prevent food contamination and foodborne illness and unsanitary conditions, it appears, we believe, providing tools, training and technologies to all food service operations is the next step in implementing food safety and safeguarding consumers. It is also imperative that operators understand the cost of the tools and the training may be an initial expense but will ultimately translate into a huge savings of time and money, given the cost of healthcare, medical treatment and lost time, not to mention loss of business due to lawsuits and safety violations.

The CHAIRMAN. Thank you. Mr. Vazzana, I'm impressed with phages but can you kind of give me a layman's explanation of what they are?

Mr. VAZZANA. They are a virus. They are the most ubiquitous organism on the planet today. They are everywhere. They are, as I said, in one milliliter, 20 drops of water, there are 200 million phages. And the only thing they do in this world, is they attack specific bacteria. So you find a phage that is effective against *E. coli*, it will go in and kill *E. coli* O157:H7 but it will not affect the phages or the bacteria around it. They are harmless, to plant cells, to human beings and to animals. They have been here and people have co-existed with this organism for billions of years.

The CHAIRMAN. Will bacteria such as Listeria develop a resistance to the phage?

Mr. VAZZANA. In theory, we believe they will. And over the billions of years, bacteria have evolved and the phages have evolved with them. So as the bacteria evolve, there will be phages that we can find that we can use on the new bacteria. We also make a product with a cocktail. So we have like six different phages in LMP 102. So as a bacteria evolves, evolves into the next phage. So we believe that bacteria will find resistance to everything that exists but we believe that there always will be a new phage that we can put in the product.

The CHAIRMAN. I just learned today that chlorine is not a kill step, when it's used in washing things. You indicate that you'd prefer to receive FDA approval under the Food Contact Substance Notification process?

Mr. VAZZANA. We believe—and I'm not an expert on government regulations and our attorneys are. I would love to have the opportunity to provide a paper on using that program and they know a lot more about it. But the problem is that it takes so long. Now the first product took 4 years and I'm the first to tell you that Intralytix was a major cause of a lot of that delay. We didn't know what FDA wanted. It was a new product or a new technology for FDA so I think they had to find out what they really wanted and that took a lot of time. But the bottom line is that after the day came when the technical review was done and it was approved, it was 18 months from that date before we finally got approval of the regulation because of all of the things that they have to do. So we want them to look at the technology and we are willing to follow

a regulation very much like the one that they have already approved but we believe that we need to get this technology out into the public and into the market so that we can play a part in improving food safety.

The CHAIRMAN. Thank you. I greatly exceeded my time and I apologize to my colleague.

Senator BURR. Mr. Chairman, that's quite all right. It's getting late so I'm going to be brief and with the Chairman's OK, I'd ask unanimous consent that we be allowed to send additional questions to them as they arise.

The CHAIRMAN. Absolutely.

Senator BURR. And I'd also like to follow up with Mr. Vazzana—since I notice you're in Baltimore.

Mr. VAZZANA. Yes, sir.

Senator BURR. I would love to invite you back to meet with my subcommittee staff to talk more in depth about phages.

Mr. VAZZANA. I would love to have that opportunity.

Senator BURR. And we would be more than happy to talk about FDA at that time, if that's okay with the Chairman and certainly the full committee staff is welcome to attend.

Mr. VAZZANA. What time tomorrow do you want to do that?

Senator BURR. I'll make sure the appropriate introductions are made before we leave and I only hope as you go through this process with FDA, you can look at the current process and realize that 4 years at the FDA is like lightening speed. So I'm curious as to the process you've gone through and we'll certainly try to help guide you in any way we can. But we'd also like to pick your brain on phages and how we might explore those in a countermeasure-way as it relates to some natural and intentional threats that we are faced with in this country.

Mr. Palmer and Ms. Crawford, thank you very much for the update on your technologies. Food dates are important. Budweiser proved that to me with the born on date on beer. People do respond to freshness and I think that will become something that even my wife should use.

I want to turn to Dr. Whitaker, if I can, because I'm still trying to clarify something from the last panel. You made the statement that this contamination is from four farms, one processor, same day product. That is pretty consistent with what Dr. Reilly said, four farms, one field, one processor—I'm not sure if he said same day. I'm still a little unsettled as to why CDC and FDA didn't spell out four farms, one processor, 1 day but I can assure you in followup questions, we will find the answer to that. Given the way you presented it, that leads one to only believe that it could happen in the wash. Given what Dr. Reilly suggested, which was one of four farms, one field, one processor, one could conclude from that, that it either happened in the wash process or there was a contamination in one field that in the processing of that one field's worth of spinach, contaminated spinach from potentially three other farms and this all happened on the same day. Can you help distinguish anything for me or have I pretty much got it right there?

Dr. WHITAKER. I think you've pretty much got it. I think the confusion may be is that the communication that we've had from FDA is that they had narrowed it down from nine farms to four farms

and that's pretty much where it stood and I think we heard today that they have found evidence of *E. coli* O157:H7 on all four farms. However, only one of those farms had the strain that was then subsequently found to be the strain that caused illness. So that may be where the confusion sits.

Senator BURR. And let me say, as empathetic as I am to the loss that you've had, the extent of where we can go, I think, is very limited. I say that because today, it's spinach and the products that you and other growers have. It's the inability to get Japan to take chicken parts because all of a sudden, there is a problem and chicken parts go bad on the ocean after a certain period of time or the beef that's in transit when we have an outbreak here and countries refuse to take our beef and the beef goes bad and processors and distributors and manufacturers eat it. So even though we're empathetic, I'm not here to optimistically tell you that even though you asked, that that is going to be one of those answers that you really like. By the same token, I hope you understand that today as we sit here, I think in retrospect, the FDA could have in a much clearer and quicker way, made the pronouncement that all spinach was safe to eat. I wanted to hear them say it today. That's why I asked them. By the same token, it should alarm you and it does alarm me that we still can't pinpoint what happened. So I can understand the reluctance over some period of time. We tried very desperately today to better understand what the appropriate period of time for this incident, for the next incident and for any incident in the future, should be. At least we've established some parameters now and my hope is that the FDA will look back on their process and will learn the downstream effects and try to mitigate that as much as they can in the future. But it does concern me today that we still can't put our finger on exactly where the contamination took place so that there can be some attempt at remediating a problem that exists. That doesn't give me a great comfort level that we might not go through a similar experience that has similar timelines and similar loss. So I hope and encourage the industry to continue to work with these agencies to try to figure out how to No. 1, eliminate the risk in the future, if that is possible. I'm not convinced it is. And No. 2, to refine their processes and how that dovetails into what you do so that we can shorten that timeframe to as short a period as we can.

With that, I thank the Chairman.

The CHAIRMAN. Thank you very much. I want to thank all of today's witnesses for their excellent testimony. I want to thank Senator Burr for his interest and attendance and also Senator Isakson. We will be emphasizing this hearing to all of our colleagues so that they will take a look at the testimony that you've provided. One of the benefits of a hearing like this is we learn a lot of things that we never knew about. Sometimes they are things that we wish we didn't know about. But mostly, they are very beneficial to helping us to understand that everybody's job is pretty tough and that there are a lot of things that we don't know about, a lot of things, and when we get some experts like you to help to enlighten us, it's a tremendous advantage. I know we don't have any further questions at this time, however all members of the committee have the right to submit questions for the record and I hope that you'll be

willing to answer those as promptly as you can. We will keep the record open for 10 days so that questions can come from my colleagues. I do have a statement from Senator Durbin and I'd ask unanimous consent to make that a part of the record of the hearing as well.

[The prepared statement of Senator Durbin follows:]

PREPARED STATEMENT OF SENATOR DICK DURBIN

Years ago, a friend from Chicago went out and bought hamburger meat at a local grocery store. She took it home, cooked it, and gave it to her 5-year-old boy. That poor boy was exposed to *E. coli* and died a few days later, a gruesome, horrible death.

In 1992, four children died and 700 people were sickened by an *E. coli* outbreak that was traced to hamburgers served at Jack in the Box restaurants. That outbreak proved to be a pivotal moment in the history of the beef industry. The Federal Government revamped the meat inspection program which has led a decline in the number of illnesses from beef since 2000.

The *E. coli* outbreak from packaged spinach that occurred just a few months ago may prove to be the critical event for the produce industry as the Jack in the Box outbreak was for the meat industry. Three people have died and 199 have been sickened in 26 States due to *E. coli* that was traced back to packaged spinach.

The Centers for Disease Control and Prevention estimate that as many as 76 million people suffer from food poisoning each year. Of those individuals, approximately 325,000 will be hospitalized and more than 5,000 will die. Children and the elderly are especially vulnerable to foodborne pathogens. Despite these statistics, our food supply is still the safest in the world; however, there are widening gaps in our food safety system due to the fact that food safety oversight has evolved over time and is spread across several agencies.

At a time when consumers are being urged to eat more fresh vegetables, it is imperative that the Government, consumer groups and those with an interest in the produce industry develop strong science-based standards that will minimize the risk of illness from fresh produce.

The produce industry has undergone many changes over the years. In the past, it was likely that produce that ended up in a local grocery store came from a farm not too far from the retailer. Fast forward to today—produce grown on a single farm in one State could end up on dinner tables in many States across the country. We are trying to use a 1950s food safety model to oversee a 21st Century food distribution system. That's like asking a propeller plane to keep up with an F–18.

As the number of foods imported from outside the United States continues to increase so do concerns that terrorists could easily attack our food supply and distribute a harmful product widely. It is more important now then ever to reinforce any potential weak spots in our food safety system.

One of the first changes that should be made is to give the agencies charged with overseeing food safety the ability to issue mandatory recalls. Consumers depend on the Federal Government to ensure that their food is safe for them and their families. The inabil-

ity of the Government to issue a mandatory recall would be like telling public health officials that they can ask—but not require—a restaurant to temporarily close if the restaurant is found to have a rodent infestation. It defies common sense. Mandatory recall authority should be a tool in the FDA's arsenal.

Next, we must implement a regular inspection program for domestic food facilities, with inspection frequency based on risk. One stark example of the inconsistency in our food safety system is the lack of standardization for food inspections—processed food facilities may be inspected once every 5 or 6 years by the FDA, while meat and poultry operations are inspected daily by USDA. This is unacceptable. Must we wait for an even deadlier *E. coli* outbreak to occur before we address the most obvious and serious weaknesses in our food safety system?

Another change that is needed is to require food producers to code their products so that those products can be traced quickly in the event of a foodborne illness outbreak in order to minimize the health impact of an event like the spinach contamination. In that outbreak, it took several weeks from the time the first illness was reported to the day the FDA issued its general warning for consumers to avoid eating packaged spinach.

Finally, we should consider a complete overhaul of the piecemeal approach our country has taken to protect the public from foodborne illnesses. We need to create a single food safety agency. Factors such as emerging pathogens, an aging population at high risk for foodborne illnesses, an increasing volume of food imports, and people eating more frequently outside their homes, underscore the need for change. The Government Accountability Office has been calling for a single food safety agency for more than 25 years. In a 1998 study, the National Academy of Sciences concluded that,

> "A model food safety system should have a unified mission and a single official who is responsible for food safety at the Federal level and who has the authority and the resources to implement science-based policy in all Federal activities related to food safety."

We need to change, to shed the old bureaucratic shackles that have tied us to the overlapping and inefficient *ad hoc* food safety system of the past and create a system fit for the 21st Century.

The CHAIRMAN. I think a lot of the questions that he has asked have been addressed in this hearing and that will be helpful as well. So again, thank you for your participation today and the hearing is now adjourned.

[Additional material follows.]

ADDITIONAL MATERIAL

PREPARED STATEMENT OF DAN VERDELLI

We at Verdelli Farms sincerely appreciate the opportunity to address this committee concerning the recent outbreak of *E. coli* O157:H7 and the subsequent effect it has had on the fresh cut industry.

Verdelli Farms is the premier East Coast regional processor of fresh cut vegetables. The company roots go back to 1921 when Ciraco Verdelli and his family settled in the Hershey, PA area and worked on a vegetable farm there. The family purchased the farm in 1943 and Ciraco's sons Albert, Bruno, and Caesar pioneered the packaging of fresh vegetables for sale in grocery stores. The company was incorporated in 1952 and produced packaged vegetables from their plant in Hummelstown, PA. In 1978 the third generation took over the daily operations and plant management. The company moved vegetable production to a new facility in Harrisburg, built to USDA Dairy regulations in 1993. With a fourth generation of the Verdelli family presently involved in the company, Verdelli Farms continues its commitment to its customers and the fresh cut industry to provide the safest, highest quality products possible.

The safety of our products has always been our No. 1 priority. We employ a full time Quality Assurance staff of food scientists and other professionals and technicians who are responsible for maintaining our food safety programs. We have a documented HACCP (Hazard Analysis Critical Control Points) plan and numerous prerequisite programs in place such as a Pest Control Program, Good Manufacturing Practices in production, and a Sanitation Program. One entire shift is devoted to sanitation to assure that our facility is cleaned and sanitized daily. The QA staff constantly monitors these programs to assure that everything is being done in the proper manner to maintain the maximum safety of all of our products. Third party audits are conducted frequently with very favorable results.

You are of course aware of the outbreak of *E. coli* O157:H7 that occurred in mid-September involving fresh spinach. A recommendation was issued by the FDA for all fresh spinach to be removed from store shelves and for consumers to refrain from consuming any fresh spinach. We, at Verdelli Farms, have the utmost respect for the FDA. With the wide variety of foods available to the American public from domestic and international sources, monitoring the safety of our food supply is truly a daunting task. However, that being said, we question some aspects of how this particular outbreak was handled.

The spinach implicated in this outbreak was baby flat leaf spinach from California. Much of the spinach that Verdelli Farms packs is curly leaf spinach. This curly leaf spinach is not grown in the Salinas Valley of California where the outbreak originated. At the time of the outbreak we were packing spinach from Colorado and have since moved into East Coast grown spinach. Throughout the year we also pack spinach from Texas and Arizona. The fact that the recommendation from the FDA did not differentiate spinach types resulted in a devastating effect on the spinach industry. A great deal of harm was done to large and small processors and growers throughout the country and it continues to affect all those involved. Verdelli Farms was forced to layoff close to 70 employees due to loss of spinach sales. Although the production is slowly returning it is a slow process and we have as yet been unable to call back any of those employees. This scenario is being repeated across the country by many processors and growers. An additional difficulty we are faced with is the inability to acquire compensation for the losses incurred by this situation. Because the action by the FDA was a recommendation rather than an official recall we have been unable to receive any insurance coverage even though clearly the effect on the company was the same.

Some of this economic loss may have been avoided if the recommendation by the FDA had been more specific and had not included the curly leaf type of spinach. In addition to the economic effects discussed above, many American consumers are now avoiding a product that is one of the healthiest, most nutritious vegetables available. And it is not only spinach sales that have been impacted. We have seen a decrease in sales of other items, also. Some consumers have developed a general mistrust of packaged fresh cut salads and vegetables. If this results in an overall decrease in vegetable consumption it is clearly detrimental to the overall health of the American public.

Verdelli Farms appreciates this opportunity to voice our opinions concerning the recent *E. coli* outbreak in fresh spinach. Again, we respect and appreciate the work of the FDA in safeguarding the health and well-being of the American public. We have simply tried to give our viewpoint on the handling of the crisis and give a gen-

eral overview of the repercussions of the FDA recommendations from our perspective. Thank you again for the opportunity to address our concerns.

RESPONSE TO QUESTIONS OF SENATOR ENZI AND SENATOR KENNEDY BY ROBERT E. BRACKETT, PH.D.

QUESTIONS OF SENATOR ENZI

Question 1. What can consumers do to prevent bacterial contamination in fresh produce? For example, will washing produce prior to consumption by the consumer remove *E. coli* and Salmonella?

Answer 1. FDA continues to emphasize consumer advice to reduce the risk of foodborne illness from fresh produce. FDA's advice to consumers is always to wash fresh, intact fruits and vegetables before consumption. While washing may not remove all bacteria, it is an important method to use to reduce the amount of bacteria that may be present.

Consumer safe handling practices begin at the grocery market and extend to include storage at home, food preparation, and kitchen sanitation. We have provided a number of safe handling practices that consumers can follow to protect themselves from illness associated with raw produce. These are available at *http://www.cfsan.fda.gov/~dms/prodsafe.html*. We mention a few of the recommendations below.

Consumers should only purchase produce that is not bruised or damaged. When selecting fresh-cut produce, such as a half watermelon or bagged mixed salad greens, consumers should choose only those items that are refrigerated or surrounded by ice. At purchase, fresh fruits and vegetables should be bagged separately from meat, poultry and seafood products when packing them to take home from the market.

At home, all produce that is purchased pre-cut or peeled should be refrigerated to 40° F or below to maintain both quality and safety. When preparing fresh produce, we recommend consumers cut away any damaged or bruised areas and thoroughly wash the produce. Drying produce with a clean cloth towel or paper towel may further reduce bacteria that may be present.

We recommend that consumers keep fruits and vegetables that will be eaten raw separate from other foods such as raw meat, poultry, or seafood and also keep them separate from the kitchen utensils used for those products.

Question 2. Are mandatory Federal and/or State food safety guidelines for farmers and processors needed to restore public confidence in fresh produce?

Answer 2. FDA is committed to improving the safety of fresh produce. FDA plans to hold a public meeting in early 2007 to address the issue of foodborne illness linked to leafy greens. We will also be examining whether improvements in the following four areas could help prevent or contain future outbreaks: (1) strategies to prevent contamination; (2) ways to minimize the health impact after an occurrence; (3) ways to improve communication; and (4) specific research. As we evaluate ways in which we can prevent or contain future outbreaks, we will consider whether additional guidance and/or regulations are necessary.

Question 3. There are a number of Federal agencies involved in food safety. Critics charge that overlapping jurisdictions and duplication of effort waste taxpayers' money and result in a fragmented system that prevents an effective focus of resources and advocate for a single agency charged with ensuring the safety of our food supply. Others argue that, by working cooperatively and through formal understandings among the agencies, Federal agencies now, for the most part, avoid duplicating efforts. Do you think a single food agency would improve the safety of our food supply?

Answer 3. No. As you are aware, the Administration looked into this issue and concluded that the food safety and food defense goals of the Administration are better advanced through enhanced interagency coordination rather than through the development of legislation to create a single food agency. The Federal food safety partners are working well with each other and with our other partners.

The government's response to the recent *E. coli* outbreak is a good example of the close and effective working relationships we enjoy with our Federal and State food safety partners. Communication between the key agencies during this outbreak investigation worked extremely well.

QUESTIONS OF SENATOR KENNEDY

Question 1a. The FDA is charged with ensuring the safety of the U.S. food, drug and medical device supply. How many inspectors does the FDA employ?

Answer 1a. In fiscal year 2006, FDA had 1,363 investigators working in all five program areas: Foods, Human Drugs, Biologics, Animal Drugs and Feeds, and Devices and Radiological Health.

Question 1b. Are inspectors segregated by field or area of expertise?

Answer 1b. FDA investigators are cross-trained to perform multiple types of inspections and may conduct any combination of inspections in the foods, human drugs, biologics, animal drugs and feeds, and devices and radiological health program areas. In addition to inspections, FDA field investigators conduct domestic and import investigations; sample collections; import field exams; recall and consumer complaint follow-ups; emergency response support (e.g., hurricanes); foodborne outbreak tracebacks/traceforwards; and, special event support (e.g., national political conventions, G8 Summit, Olympics). Additional expertise in various program areas is obtained by some investigators as their careers advance.

Question 1c. How many FDA inspectors are devoted to food safety inspections?

Answer 1c. In fiscal year 2006, FDA had 640 investigators working in the foods program.

Question 1d. How does training of food inspectors differ from other FDA inspectors?

Answer 1d. All FDA investigators are required to successfully complete a common foundation of training (i.e., "New Hire"), exercises, and On-the-Job Training (OJT) within an investigator's first 12 months of employment. Training includes topics such as Food and Drug Law, Import Operations, FDA Establishment Inspection, Sample Collection, Aseptic Sampling, Good Manufacturing Practices for food, Field Examinations, Interviewing Techniques, Evidence and Proof, FDA Establishment Report Writing, Courtroom Testimony, Food Microbiological Control, Recalls of FDA Regulated Products, Destruction and Reconditioning, FDA Laboratory Orientation, and Special Investigations. At the completion of the New Hire Curriculum, each investigator is required to successfully complete a field audit conducted by a standardized auditor and is then designated a Level I Certified Investigator.

Once the investigator completes the Level I Investigator certification, each is provided higher level training related to the regulated industries for which he/she will eventually conduct inspections. FDA regulates a broad breadth of industries—human drugs, veterinary drugs, medical devices, biologics, and foods. Each of these program areas has its own specific regulations and inspectional policies and procedures that are based on the science and risk associated with that particular commodity. These regulations, policies, and procedures serve as the basis for the training. The training is delivered in the form of web-based training, OJT, and class room courses. Some of the topic areas of courses associated with foods include: Foodborne Illness Investigations, Produce Farm Investigations, Tracebacks (produce), Seafood HACCP, Juice HACCP, Dairy HACCP, Basic and Advanced Low Acid Canned Foods, Acidified Foods, Food Code, Shellfish, and Dairy Products.

Question 1e. In the previous year how many inspections were conducted at farms in the United States; in the Salinas Valley of California?

Answer 1e. In fiscal year 2006, 22 growers (farms) of "fresh" vegetables and fruits were inspected by FDA and an additional 3 by the States under contract to FDA or under partnership with FDA. In addition, in fiscal year 2006, CalFERT investigated 8 farms as part of a foodborne illness outbreak investigation in Salinas Valley. CalFERT (California Food Emergency Response Team) is a joint California and FDA response team.

Question 1f. In the previous year how many inspections were conducted at processors of produce grown in the United States; in the Salinas Valley of California?

Answer 1f. In fiscal year 2006, 442 processors (manufacturers or repacker/packers) of "fresh" vegetables and fruits were inspected by FDA and an additional 322 by the States under contract to FDA or under partnership with FDA.

In fiscal year 2006, 23 Salinas Valley processors (manufacturers or repacker/packers) of "fresh" vegetables and fruits were inspected by FDA.

Question 2a. In August 2006, the FDA in conjunction with the California Department of Health Services began its Lettuce Safety Initiative. Part of this initiative was to visit farms, processors and packagers of fresh produce in California. How many inspections were planned as part of this initiative?

Answer 2a. Thirty-five to forty total operations, specifically assessments and inspections, were planned under the Lettuce Safety Initiative Assignment with em-

phasis placed on the following operations in priority order: harvester assessments, processor inspections, and cooler/packer/shipper assessments.

Question 2b. How many inspectors were assigned to conduct these inspections?

Answer 2b. Three CalFERT investigators conducted inspections and three CalFERT investigators conducted assessments.

Question 2c. What were the specific goals of these inspections and what areas of expertise did the FDA inspectors possess?

Answer 2c. The goals of inspections and assessments were as follows: reduce public health risk associated with an FDA-regulated product by focusing on the product, agents, and areas of greatest concern; assess adoption and implementation of Good Agricultural Practices (GAPs); assess awareness and degree of adoption of lettuce specific commodity guidance; assess the use of Good Manufacturing Practices (GMPs); and document observations that identify practices that potentially lead to product contamination in order to develop and/or refine guidance and policy that will minimize opportunities for future outbreaks and/or identify research needs. Investigators assigned to perform inspections possessed knowledge, skills and abilities to analyze and evaluate data and practices in order to determine and document compliance and/or deficiencies with respect to the FD&C Act and regulations. Investigators assigned to perform assessments also possessed the aforementioned knowledge, skills and abilities, and had received formal training in produce farm investigations.

Question 2d. What was the timeframe for the inspection portion of the Lettuce Safety Initiative? What was the timeframe for the analysis and implementation of any recommendations?

Answer 2d. The inspection portion was intended to continue until 35–40 operations were completed or until end of harvest season, which typically ends in November each year.

The Lettuce Safety Initiative Assignment was placed on hold due to the spinach *E. coli* O157:H7 outbreak investigation, which began on September 13, 2006. Upon receiving notification of the outbreak, resources were redirected to the outbreak investigation and work. Approximately 30 operations (inspections and assessments) were completed by September 13, 2006.

Question 2e. Given that these inspections had to be canceled due to the outbreak of *E. coli* O157:H7 contaminated spinach when does the FDA plan on resuming these inspections?

Answer 2e. FDA's San Francisco District anticipates that work will resume on the Lettuce Safety Initiative during the next harvest season.

Question 3a. The Public Health Security and Bioterrorism Preparedness Act of 2002 granted the FDA significant new authorities over domestic food products and production. Did these new authorities help speed the Federal response to this outbreak?

Answer 3a. Among other provisions, section 306 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (BT Act) provided FDA with important new authority to require the establishment and maintenance of records by persons who manufacture, process, pack, transport, distribute, receive, hold, or import food. It further required persons to provide FDA with access to certain records during public health emergencies. As part of the traceback investigation, FDA reviewed records held by a number of firms, including warehouses, packers, processors, and farms. Firms were cooperative and voluntarily provided the records FDA requested; thus, FDA did not need to invoke its records access authority under the BT Act. (As you know, farms are not covered by the recordkeeping provisions of the BT Act.) It is possible that not all of the records we were provided would have existed in the absence of the BT Act's recordkeeping requirement.

Question 3b. Had all of the implicated companies complied with the registration requirements?

Answer 3b. Earthbound Farm (processor) and Pride of San Juan (grower, warehouse, packer/re-packer) both in California were found in the registration database. Natural Selection Foods, LLC, (processor) in San Juan Bautista, California is registered under the name Earth bound Farm. The statute exempts farms from the registration requirement.

Question 3c. How useful was the "one-step forward, one step back" recordkeeping requirement in identifying the course of the contaminated product from farm to table?

Answer 3c. This requirement is very helpful. As noted above in our response to 3(a), FDA obtained records from the processor and used those records to trace back to the growers and fields.

Question 3d. Farms are specifically exempted from the registration requirements under this act. Would registration of farms have aided in the outbreak detection and mitigation process?

Answer 3d. In this particular situation, we do not believe information that would have been available through registration of farms would have been necessary. Because of the specific information on bags of spinach and information provided by processors, FDA was able to obtain the information needed to identify the implicated farms. However, as we continue to evaluate what additional measures may be needed in the future, we will be considering whether any additional registration information would be helpful.

Question 3e. Should farms that grow Ready-to-Eat produce which necessarily require less processing be required to register?

Answer 3e. We are still in the process of evaluating what additional measures may be necessary to help prevent future outbreaks and minimize any that occur.

Question 4. FDA has required all seafood processors to implement a Hazard Analysis Critical Control Points (HACCP) plan. Where does the legal authority for this action reside? Does FDA have the authority to require ready-to-eat produce growers, processors and packagers to design and implement Hazard Analysis Critical Control Points (HACCP) procedures? If so, where statutorily does this authority derive from?

Answer 4. FDA issued the seafood HACCP regulation under various sections of the Federal Food, Drug, and Cosmetic Act (FD&C Act), primarily sections 402(a)(1), (a)(4) and 701(a) (21 U.S.C. 342(a)(1), (a)(4), and 371(a)) and the Public Health Service Act, primarily section 361 (42 U.S.C. 264). (For further discussion of the legal basis for the seafood HACCP rule, see 60 FR 65095 (Dec. 18, 1995) and 59 FR 4142 (Jan. 28, 1994)). Section 402(a)(1) of the FD&C Act provides that a food is adulterated if it bears or contains any poisonous or deleterious substance that may render the food injurious to health. Section 402(a)(4) of the FD&C Act provides that a food is adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health. Section 701(a) of the FD&C Act authorizes the agency to adopt regulations for the efficient enforcement of the act. In addition, the Public Health Service Act authorizes FDA to make and enforce regulations to prevent the introduction, transmission, or spread of communicable disease.

The FD&C Act provides a broad statutory framework for Federal regulation to ensure human food will not be injurious to health and to prevent commerce in adulterated foods. Further, the Public Health Service Act provides FDA with broad authority to issue regulations necessary to control the spread of communicable disease. For FDA to use these authorities to mandate HACCP in a particular circumstance, the agency must demonstrate a strong scientific basis to establish that such requirements are necessary to prevent food from being adulterated or to control the spread of communicable disease. The investigation into the recent *E. coli* outbreak is not yet completed. Once we have completed our current investigation, FDA will hold a public meeting to address the larger issue of foodborne illness linked to leafy greens. We also will examine whether improvements in the following four areas could help prevent or contain future outbreaks: (1) strategies to prevent contamination; (2) ways to minimize the health impact after an occurrence; (3) ways to improve communication; and (4) specific research. In addition, we will hold a series of meetings with industry groups to discuss ways to improve the safety of fresh produce. We will use all of this information to determine whether additional requirements are necessary and within FDA's authority to ensure the safety of ready-to-eat produce.

Question 5. Dr. Reilly, of the California Department of Health Services Prevention Services, testified that "The Salinas Valley appears to have systemic *E. coli* O157:H7 contamination in the environment that has led to a number of fresh produce associated outbreaks over time." The beef industry in its zero tolerance efforts to reduce *E. coli* contamination uses a "test and hold" procedure whereby a meat product is held while tests for the presence of *E. coli* O157:H7 are conducted. Does FDA posses the authority to require "test and hold" procedures to assure that fresh produce is safe to eat?

Answer 5. We understand your question to be referring to voluntary testing of meat products for *E. coli* O157:H7 by the beef industry. The produce industry similarly could implement a voluntary test and hold procedure for fresh produce. The

investigation into the recent *E. coli* outbreak is still ongoing, and FDA is still gathering information to determine what future actions, including regulation, may be necessary and within its authority to ensure the safety of ready-to-eat produce. FDA notes, however, that *E. coli* O157:H7 is not uniformly distributed in food and that even the presence of a very small amount of *E. coli* O157:H7 can cause illness. Therefore, testing cannot completely "assure that fresh produce is safe to eat."

Question 6. Dr. Reilly noted in his testimony that the fields that were the source of the contaminated spinach were located in an area of concern for the California Department of Health Services. If it was determined that a certain field or area was a persistent or recurring source of contamination, does FDA have the authority to restrict or direct that produce from these areas be prohibited from entering the food distribution system as Ready-to-Eat?

Answer 6. Under the FD&C Act, adulterated food cannot be sold in interstate commerce, 21 U.S.C. 331(a), and is subject to regulatory action, such as seizure, 21 U.S.C. 334. Several adulteration provisions of the FD&C Act are potentially applicable to the circumstances described in the question. For example, food is adulterated if it bears or contains any poisonous or deleterious substance that may render the food injurious to health, 21 U.S.C. 342(a)(1). In addition, food is adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health, 21 U.S.C. 342(a)(4). If FDA could establish that produce is adulterated, FDA would have authority to prohibit its distribution in interstate commerce.

Question 7. During the hearing we heard from both Dr. Reilly and Dr. Whitaker that more research is required into the etiology and ecology of bacterial pathogens. What efforts to fund intra- and extramural research into bacterial contamination of fresh produce has the FDA undertaken?

Answer 7. FDA's food safety research approach is threefold, involving an intramural program, and extramural program, and consortia with industry and/or academia. Additionally, to prioritize research needs and avoid duplication, FDA coordinates with its sister agencies within HHS, such as CDC, and with other Federal partners such as USDA.

As we discussed in our testimony, our current research agenda is focused on improving the identification and detection of disease-causing bacteria and toxins in a variety of foods. We are also studying possible intervention strategies, such as the use of thermal treatment and irradiation, which could be applied to fresh produce products to reduce the level of bacteria and viruses that are in or on the product.

Some recent accomplishments on the subject of produce research include:

- Provided technical assistance to State, university, and industry efforts to plan research, risk assessments, and education outreach to enhance the safety of fresh produce.
- Collaborated with industry, in cooperation with State agencies and academia, to develop commodity-specific supply chain guidance for the commodities that have most often been associated with foodborne illness outbreaks (cantaloupe, lettuce/leafy greens, and tomatoes). We are working to finalize guidance on herbs and green onions.
- Issued the "Draft Guidance: Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables" in March 2006. The guidance contains recommendations to help fresh-cut produce processors reduce the risk of microbial contamination in their products and provides the agency's recommendations for control of hazards as they apply to fresh-cut produce. The agency expects final guidance to issue in fiscal year 2007.
- Conducted and supported research focused on: (1) identifying mechanisms of contamination of fresh produce with pathogens and preventing contamination; (2) identifying effective interventions to address contamination that has occurred; and (3) developing fast and sensitive analytical methods for the detection of pathogens on fresh produce.
- Developed a risk profile for *Listeria monocytogenes* in fresh produce.
- Started a risk profile for hepatitis A in fresh produce.

FDA funded an interagency agreement with USDA/ARS to provide additional support to an ARS research project entitled "USDA and FDA Collaborative Effort for the Study of *E. coli* O157:H7 in Pre-harvest Produce Environment." This study was conducted from October 1, 2005 through September 30, 2006 and analyzed water samples from the Salinas watershed for *E. coli* O157:H7.

FDA has also provided technical assistance to USDA/CSREES in the development of the recent Integrated Research, Education, and Extension Competitive Grants

Program—National Integrated Food Safety Initiative solicitation (see *http://www.csrees.usda.gov/funding/rfas/food_safety.html*).

FDA/CFSAN has two consortia partnerships, leveraged through extramural cooperative agreements, that are involved in produce safety research. One partnership, the Joint Institute for Food Safety and Applied Research (JIFSAN), is with the University of Maryland, College Park. JIFSAN produce-related collaborative projects are available at *http://www.jifsan.umd.edu/annualrep.htm*.

Another partnership, the National Institute for Food Safety and Technology (NCFST), is with the Illinois Institute of Technology and numerous food industry members and focuses on prevention and intervention research. Research conducted at NCFST has significantly supported the development of FDA's policy and regulatory response for juice HACCP and the safety of sprouted seeds and apples. NCFST annual reports, including publications in the public domain, are available at *http://www.ncfst.iit.edu/main/home.html*.

FDA's produce-related research priorities currently under consideration include:

(1) optimizing procedures for the recovery of virus particles from produce to integrate into detection methods;

(2) methods for accurate identification and subtyping of *E. coli*, Salmonella, and Shigella pathogens;

(3) monitoring of irrigation or wash waters and development of rapid detection assays; and,

(4) assessing survival and/or growth of pathogens in packaged produce.

Question 8a. There remains an outstanding scientific question regarding the ability of farm produce to internalize bacterial contamination via absorption from contaminated fields and/or ground water. This potential source of contamination poses a unique threat to the public, since such contamination could not be removed or mitigated during normal processing procedures. What efforts has FDA taken to answer this question?

Answer 8a. FDA/CFSAN's NCFST consortia partner has conducted intervention studies on apples with internalized *E. coli* O157:H7. FDA has indicated that the role of bacterial contamination via adsorption from contaminated fields and/or ground water is a priority research need and has communicated this in the Produce Safety Action Plan and to the USDA research agencies and other stakeholders through meetings, the Lettuce Safety Initiative, and the November 30, 2006 Tomato Summit in Orlando, Florida, for example.

Question 8b. If internalization of harmful bacteria does occur would this constitute adulteration?

Answer 8b. Food is adulterated if it bears or contains any poisonous or deleterious substance that may render it injurious to health, 21 U.S.C. 342(a)(1). Food described in the question, that is, produce that contains harmful bacteria that "could not be removed or mitigated during normal processing procedures" contains a deleterious substance and would be adulterated under the FD&C Act.

Question 8c. If such internalization occurred does the FDA possess the authority to require farms to certify that effective measures to prevent or mitigate such contamination take place?

Answer 8c. Under the FD&C Act, producers of food, including farms, are responsible for ensuring that the food they produce is not adulterated. Producers bear this responsibility regardless of any certification they might make and are subject to injunction, criminal penalties, and seizure of their food for violations of the FD&C Act, such as causing food to become adulterated. Therefore, FDA usually does not rely on broad certifications to ensure the safety of food. Generally, FDA has authority to require that farms take measures necessary to prevent food from becoming adulterated and to prevent the spread of communicable disease.

Question 9a. Dr. Reilly testified that fields that were the source of the contaminated spinach remain "disked under." Was this a voluntary action by the farmers or was this mandated by the FDA, by California?

Answer 9a. Two of the four implicated fields were barren. The remaining two fields contained product; however, the farmers voluntarily agreed to plow under the fields.

Question 9b. What is the role of FDA in determining if produce from these fields should/can be allowed to be reintroduced into the Nation's food supply?

Answer 9b. When specific fields or facilities are implicated in a foodborne illness outbreak investigation, FDA works with State officials and the firms involved to help ensure the safety of produce from these sources.

Question 9c. Does FDA posses the authority to prevent these fields from returning to production if nothing is done to address the concerns of contamination?

Answer 9c. The investigation into the recent *E. coli* outbreak is still ongoing, and FDA is still gathering and analyzing information related to the conditions on the implicated fields. If FDA were to determine that any spinach grown on a particular field would be adulterated because of the conditions on that field, then the adulteration prohibitions of the FD&C Act would be applicable, such as the prohibitions against introducing adulterated food into commerce, 21 U.S.C. 331(a), and against adulterating any food in interstate commerce, 21 U.S.C. 331(b). Further, adulterated food is subject to seizure, 21 U.S.C. 334.

Question 10. Mr. Brackett testified that the FDA has learned more from this outbreak than all other previous outbreaks combined. What is the timeframe for the FDA's investigation and subsequent recommendations?

Answer 10. CalFERT expects to conclude the field investigation in December 2006 and expects to complete the comprehensive investigation report in February 2007.

Question 11a. Mr. Reilly cites various sources of potential *E. coli* contamination. Two of these sources, manure used for fertilization and field proximity to infected livestock, raise important concerns regarding the use of antibiotics in animal feed stock. As the FDA recognized in 2005 when it banned the use of fluoroquinolones to treat sick poultry, the use of certain drugs in animals can adversely affect the ability to use these (or related) drugs to treat humans. Does the FDA have the legal authority to place extralabel use restrictions on an animal drug prior to the drug's being marketed when either a drug sponsor's own risk assessment or an internal FDA risk assessment finds that a potential drug approval presents a high risk of resistance adversely affecting human health? If so, has the FDA ever used this authority? If not, would it promote the public health if the FDA had such authority?

Answer 11a. FDA issued an order in May 1997 (62 FR 27944) to prohibit the extralabel use of fluoroquinolone and glycopeptide drugs in food-producing animals. At the time of issuance of that order, fluoroquinolone drugs were approved and marketed for use in certain animal species. Although certain glycopeptide drugs were approved for use in humans at that time, no glycopeptide drugs were approved or marketed for use in animals nor are any drugs in the glycopeptide class approved for use in animals today. More recently, FDA issued an order in March 2006 (71 FR 14374) to prohibit the extralabel use of the anti-influenza adamantane (amantadine and rimantadine) and neuraminidase inhibitor (oseltamivir and zanamivir) drugs in chickens, turkeys, and ducks. Although these anti-influenza drugs are approved for use in humans, these drugs are not approved or marketed for use in animals. Therefore, based on resistance concerns, FDA has previously prohibited the extralabel use of drugs that have not been approved for use in animals when FDA has found that the extralabel use of the drug in animals presents a risk to public health.

Question 11b. Does the FDA now require drug sponsors to carry out pre-approval studies to determine potential resistance problems that are likely to occur if a drug is approved?

Answer 11b. Prior to approving a new animal drug application, FDA must determine that the drug is safe and effective for its intended use in the animal. The Agency must also determine that an antimicrobial new animal drug intended for use in food-producing animals is safe with regard to human health (21 CFR 514.1(b)(8)). FDA considers an antimicrobial new animal drug to be "safe" if it concludes that there is reasonable certainty of no harm to human health from the proposed use of the drug in food-producing animals.

FDA published guidance for industry (GFI #152) on this issue in October 2003 entitled, *Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern*. This guidance document outlines a risk assessment approach for evaluating the microbial food safety of antimicrobial new animal drugs intended for use in food-producing animals. Alternative processes that may be more appropriate to a sponsor's drug and its intended conditions of use, may also be used to characterize the microbial food safety of that drug. FDA considers this information when evaluating drug safety as part of the new animal drug approval process.

Question 11c. In early 2004, FDA raised with the drugs' sponsors that several approvals for the use of penicillin in animal feeds are inappropriate due to concerns about antimicrobial resistance, but it has subsequently taken no action to withdraw these approvals. Does FDA have the legal authority to withdraw approvals of ani-

mal drugs that the agency has determined present a high risk of resistance adversely affecting human health in a timely manner?

Answer 11c. FDA has the authority to withdraw the approval of a new animal drug application, however the agency must first notify the holder of the application and afford an opportunity for a hearing on the proposal to withdraw such application. The agency can initiate such proceedings if evidence shows, for example, that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved.

In addition, the Secretary may suspend approval of a new animal drug application if the Secretary finds that there is an imminent hazard to human or animal health. The Secretary must give the applicant notice of such action and afford the applicant the opportunity for an expedited hearing on the suspension. This authority cannot be delegated.

Question 12a. The regulations governing FDA advisory committees require that FDA keep either detailed minutes of all advisory committee meetings or less detailed minutes when a transcript of the meeting is to be made available. These minutes are to include among other things a complete and accurate description of matters discussed and conclusions reached. 21 CFR 14.60(b)(4) The accuracy of the minutes is to be approved by the committee and certified by the Chairman. 21 CFR 14.60. The summary available at the FDA's Website for the VMAC Winter 2005 meeting is described as the Acting Chairperson's Summary. Are these considered by the FDA to be the official minutes of the meeting?

Answer 12a. CVM relies on the transcript of the VMAC as the official record of the meeting. The Chair's summary has historically been posted prior to availability of the transcript as a means of informing the public that the meeting was held and to describe the matters discussed and conclusions reached.

Question 12b. If the summary described above is not the official minutes of the meeting then were they approved pursuant to 21 CFR 14.22(i)(4) which states that notes, minutes or reports prepared by a committee member have no status or effect unless adopted into the official minutes by the committee.

Answer 12b. The Chair's summary is not the official minutes of the meeting and was not adopted into the official minutes by the committee. The Chair's summary is intended to summarize the meeting as a convenience for the public prior to availability of the transcript but are not part of the official record.

Question 12c. Please describe the process that the Center for Veterinarian Medicine uses in the preparation and dissemination of the minutes of VMAC committees and compare them to the processes used by other FDA advisory committees. For instance, the minutes from CDERS Antiviral Drugs Advisory Committee meetings present a detailed tally of each of the votes taken by the advisory committee.

Answer 12c. CVM, as do the other FDA Centers, relies on the transcript of its advisory committee meetings as the official record of the meeting. Transcripts are posted on FDA's Website. CVM's executive secretary does not prepare detailed minutes of the meetings.

RESPONSE TO QUESTIONS OF SENATOR ENZI AND SENATOR KENNEDY BY LONNIE J. KING, D.V.M.

QUESTIONS OF SENATOR ENZI

Question 1. I am very interested in the 2004 Produce Safety Action Plan. I recognize that much of this plan rests with FDA and the industry, but CDC has an important role to play. What is needed to help your agency fulfill its role in the collection and analysis of outbreak surveillance data to help assess the impact of the Action Plan?

Answer 1. As regulatory processes develop, it is critical to include objective external assessments of their impact. Public health surveillance data are an important way to track the success of prevention plans that target either specific disease-causing pathogens or specific foods. The quality and usefulness of outbreak reports, like all surveillance data, depend critically on the resources, training, and skills of the primary public health officials in local and State health departments, who investigate the vast majority of the over 1,000 foodborne outbreaks investigated each year and who report the results of those investigations. Resources permitting, CDC could conduct analysis of data to present annual summaries of reported produce-related outbreaks in general, with specific analyses on leafy greens, tomatoes, melons, sprouts, spring onions, and juice.

Question 2. How does CDC draw the line between a cluster and an outbreak?

Answer 2. The distinction lies in the public health investigation. For foodborne diseases, CDC defines a cluster as a group of people with the same illness that may possibly be related. For example, a cluster of illness may be an unexpectedly high number of cases in a particular time and place that are caused by the same subtype of pathogen. After a cluster is detected, an investigation may define a particular common source or exposure. Such clusters are then called outbreaks. Thus, an outbreak is a cluster of illness that has been investigated, and shown to be related to a particular exposure the group had in common, such as eating a particular food, or eating in one particular restaurant. Clusters can be investigated in several ways, and the decision of which clusters to investigate and which methods to use is a major part of the science of field epidemiology.

Question 2a. Do the cases have to be multistate or multisite to be considered an outbreak?

Answer 2a. They do not. Foodborne outbreaks come in many shapes and sizes, depending on the nature of the contamination event. When a food is contaminated and mishandled in one kitchen, the outbreak will affect just those persons that ate foods from that kitchen, who may be one family, company, school, catered reception, or the patrons of one restaurant. If a food is contaminated earlier in the food chain, for example on the original farm or early in the processing, and then is distributed to multiple kitchens and served to many different people in many settings, then the outbreak will affect persons scattered across a wide area, depending on how that food was distributed.

Question 2b. How and when does CDC determine that a multistate *E. coli* outbreak has occurred?

Answer 2b. This can occur in several ways. Persons who are investigating local clusters may realize that their outbreak may be associated with a nationally distributed food, and a broadened search for cases identifies other cases around the country that are part of the same outbreak. Sometimes there are separate local investigations that independently come to similar conclusions, and it then becomes apparent that the two clusters are part of the same larger outbreak. Sometimes an increase in infections caused by a specific type of pathogen may be noted over a wide region, without a local outbreak to call attention to it. Public health capacity to link together the apparently separate outbreaks and cases has been greatly improved in recent years by application of DNA fingerprinting to the bacteria themselves.

CDC has developed and directs PulseNet, a public health laboratory network operational in all 50 States and in Federal food regulatory agencies. The laboratories in PulseNet conduct DNA "fingerprinting" of *E. coli* O157 and other bacteria, add those fingerprints to the national database at CDC, and compare the fingerprints with others being identified in other States. When two clusters in different States turn out to have the same pattern, or when an unexpectedly large number of infections with the same fingerprint show up in multiple States, PulseNet recognizes this as a multistate cluster. This cluster will be investigated, usually in collaboration with OutbreakNet (the network of epidemiologists in the local and State health department and CDC who investigate foodborne disease outbreaks). If a common food or other source is identified by the investigation, then the multistate cluster becomes a multistate outbreak. It can also happen that an apparently local outbreak, detected and investigated in one jurisdiction, is the initial event of a larger outbreak. Therefore, CDC encourages reporting of local outbreaks and adding the PulseNet fingerprints of all outbreaks, large and small, to the database. CDC has developed extensive communication networks so that State health officials can report clusters and outbreaks rapidly to CDC and to each other. Frequent communication about suspected outbreaks and food vehicles is enhanced by formal and informal communication channels, including the foodborne outbreak listserv maintained by CDC's OutbreakNet epidemiologists, EpiX notifications, direct phone calls, and the PulseNet web-board.

Many of the infections transmitted by contaminated food are also transmitted through water, or directly from animals, or by other ways. Thus, finding a cluster of *E. coli* O157 infections does not automatically mean there is a contaminated food source. However, as soon as there is a suspicion about a particular food, CDC informs the appropriate Federal regulatory agency, so they are aware of the investigation and begin to play their part.

Question 2c. When did CDC determine in the recent case of bagged spinach that a multistate outbreak had occurred?

Answer 2c. A multistate outbreak related to spinach was judged likely on September 13, and conclusively on September 14. CDC was first informed on September 8 of a local cluster of *E. coli* O157 infections in Wisconsin that had been detected by local case surveillance and by a limited number of PulseNet patterns linking local cases. On that day, Wisconsin posted the DNA "fingerprint" pattern on the general PulseNet communication Website, making it available to all PulseNet participants, including all other States, CDC, and regulatory agencies. At that time, there was no unusual number of recent postings of this pattern among other States. That same day, the Wisconsin State epidemiologist called the head of CDC Foodborne Outbreak Response and Surveillance Team to discuss the cluster, and the investigative approach Wisconsin was taking. By September 13, the investigation in Wisconsin had progressed and suspicion was increasing about several possible foods, including leafy greens and a fruit. That same day, epidemiologists in Oregon contacted CDC to discuss a very small cluster of cases they were investigating that they thought might have an association with leafy greens. An ad hoc conference call by CDC immediately connected Oregon and Wisconsin investigators; during that call the two States realized that they both were particularly suspicious of spinach. At the end of that call, the CDC epidemiologist called FDA officials to inform them that there appeared to be a multistate cluster with the strong possibility that fresh spinach was the source, and through the foodborne outbreak listserv, all 50 States were notified of the possible connections. The next day, September 14, CDC held a conference call among the State foodborne epidemiologists of OutbreakNet to gather further information. By the end of that call, a number of States had reported cases with the same DNA fingerprint, for which investigations indicated a strong association with fresh spinach. The speed of moving from identification of a local cluster (on September 8) to detection of a multistate cluster (September 13) to identification of a multiple State outbreak strongly associated with a particular food (September 14) was extremely swift.

Question 3. How many *E. coli* cases are reported to CDC on a day-to-day basis?

Answer 3. Approximately 3,400 *E. coli* DNA "fingerprint" patterns are uploaded to the CDC PulseNet database each year. The infection is seasonal, with a peak in the late summer and early fall, and relatively few in the colder months. During a typical September, PulseNet receives reports of 440 *E. coli* O157 patterns, or 20 per working day.

Question 3a. How many of these are *E. coli* O157:H7 cases?

Answer 3a. Of these, approximately 87 percent are reported as *E. coli* O157:H7, 9 percent are reported with a serotype other than O157:H7, and 4 percent with serotype undetermined or pending. Other *E. coli* serotypes besides O157:H7 can cause similar illness, but they are less frequently recognized by clinical diagnostic laboratories and reported to State Health Department Laboratories. CDC is currently planning to increase capacity in State public health laboratories to detect and identify these other *E. coli*.

Question 3b. How does the background level of *E. coli* cases reported influence the determination of whether or not an outbreak is occurring?

Answer 3b. Most reported cases of *E. coli* O157 infection are so-called sporadic cases that do not have an apparent connection to any cluster. Detecting a cluster among the sea of sporadic cases is similar to picking out a radio signal from the background static noise. If the background level of cases is high, then a large surge in cases is needed to stand out above the background level. Part of the power of the PulseNet system is its ability to make a signal stand out from the background noise, thus making cluster detection easier. The PulseNet database contains hundreds of different *E. coli* O157 patterns. Some patterns are common, others are rare. For example, if a cluster of 15 ill persons occurs that is spread across several States in a week, it may be hard to identify against the background of 100 cases that might be reported that week. However, if the 15 *E. coli* strains have identical fingerprint patterns, they may stand out easily against the background of the 5 cases with that pattern that might usually be reported in a week. Thus, PulseNet makes it possible to detect clusters that would otherwise be missed, and can detect some clusters when they are small, that would otherwise not be detected until they grew large.

Once an investigation of a cluster begins, PulseNet similarly can play a critical role in defining which cases to include in the investigation. This can greatly improve the efficiency and speed of the investigation, because it means that the OutbreakNet investigators can concentrate the investigation on the cases with matching fingerprints patterns, thus increasing the likelihood of pinpointing the cause of illness.

QUESTIONS OF SENATOR KENNEDY

Question 1. What is the current classification of the death of June Edith Dunning, the Maryland resident who died on September 13th and is suspected to be a fourth fatality in the recent outbreak?

Answer 1. That fatal case is classified as a "suspect case." In the outbreak of *E. coli* O157:H7 infection due to spinach, CDC, State and local investigators agreed to working case definitions, including definitions for confirmed and suspect cases. A confirmed case required either an *E. coli* O157 isolate demonstrating the outbreak strain DNA fingerprint pattern as determined by pulsed-field gel electrophoresis (PFGE), or consumption of spinach that when cultured yielded the outbreak strain of *E. coli* O157. It was also agreed that cases with *E. coli* O157 infection without isolate PFGE information and who had consumed raw spinach (of which no culture was available) were classified as suspect cases.

The outbreak investigation is not yet closed. To date, CDC has released only confirmed case counts in summary statistics concerning this outbreak. Future reports, however, will include details concerning both confirmed and suspect cases.

Question 2. The classification of Judith Dunning's death seems to have been complicated by a number of institutional mistakes including a lost or unaccounted sample. Are these mistakes indicative of systemic problems with the outbreak detection apparatus?

Answer 2. This case was the subject of an intense investigation at local, State and Federal levels. The patient was initially diagnosed with a different illness, and later diagnosed with *E. coli* O157. Although it had been identified in the clinical laboratory, the *E. coli* strain isolated from the patient was not retained or forwarded to the State public health department laboratory. Later efforts to recover *E. coli* O157 from the discarded laboratory diagnostic plate, from a biopsy specimen, and from leftover food were unsuccessful. Foodborne outbreak detection and investigation depends in part on submitting strains of *E. coli* O157 and other pathogens from clinical diagnostic laboratories to State laboratories for PulseNet fingerprinting. Some States require this submission to be done routinely, while others request it but do not make it mandatory.

Maryland regulations require the clinical laboratory director to report the isolation of *E. coli* O157:H7. Sending an *E. coli* O157:H7 isolate to the State public health laboratory is routinely requested but is not mandatory. The laboratory associated with this case has routinely submitted isolates in the past. Although it is not clear that a requirement for routine submission of *E. coli* isolates would have influenced the specific sequence of events in Maryland, this issue reflects the broader need to strengthen systems for submission and analysis of isolates as a vital part of public health surveillance in all States.

Question 3. Were sufficient laboratory personnel and equipment available to monitor the outbreak?

Answer 3. The large *E. coli* O157 outbreak traced to spinach stretched resources at local, State and Federal levels. Investigative capacity was found by borrowing resources from other food safety programs, and by CDC personnel conducting some interviews with cases and healthy controls on behalf of health authorities in some States. Laboratory capacity was strained even further, and in particular the capacity of local and State health department laboratories to rapidly transfer the *E. coli* O157:H7 strains from patients, to the public health laboratory by courier, to fingerprint them and to upload the fingerprint patterns to PulseNet. However, even with these adjustments, the response to this outbreak illustrates the importance of existing public health networks and demonstrates what a robust public health system can accomplish.

RESPONSE TO QUESTIONS OF SENATOR ENZI AND SENATOR KENNEDY
BY KEVIN REILLY, D.V.M., M.P.V.M.

QUESTIONS OF SENATOR ENZI

Question 1. There is a history of outbreaks of foodborne illness traced to produce grown in California's Salinas Valley dating back to 1995. Why is this area so susceptible to *E. coli* contamination?

Answer 1. Although 9 of 20 outbreaks of *E. coli* O157:H7 associated with green leafy produce have been traced back to the Salinas Valley in the past 11 years, multiple farms have been implicated, and no single risk factor has emerged to explain this association. A large proportion of the commercial sale of lettuce, spinach and other green leafy vegetables across the country comes from the Salinas Valley. We

know that *E. coli* can contaminate produce on the farm in several ways: through irrigation or other (flooding) water sources, fertilization (uncomposted manure), poor farm worker hygiene, contamination from wildlife carrying the bacteria, or contamination from domestic animals (cattle) carrying the bacteria. The science is not yet completed on how these factors come together in this region to result in contamination reaching the produce in the fields and ultimately surviving processing at levels that lead to foodborne illness outbreaks.

Question 2. How are the California Department of Health Services and the California produce industry working to develop a longterm plan to prevent these foodborne outbreaks? What are the obstacles to developing a comprehensive longterm plan? What metrics could be developed for the plan to determine how well it is working?

Answer 2. CDHS has been working with FDA and Industry for several years. Recently, the California produce industry submitted a proposal to implement mandatory Good Agricultural Practices (GAPs) as a requirement under a "Marketing Order" program being developed by the industry. CDHS is currently reviewing this proposal that includes specific metrics for risk factors such as water, compost, and proximity to livestock operations. Obstacles include a lack of research in many areas including how pathogens come into contact with ready to eat produce, how pathogens survive or grow in the environment, and what additional processing measures can be taken to reduce the risk of contamination.

QUESTIONS OF SENATOR KENNEDY

Question 1. How many inspectors does California employ to monitor food safety? How many times a year are farms inspected and do these inspections take into account that Salinas California apparently has an increased likelihood of producing contaminated produce?

Answer 1. The California Department of Health Services employs approximately 42 Food and Drug Investigators with peace officer status to inspect processed food facilities, canneries and wholesale food facilities statewide. In addition, county public health and environmental health departments employ several hundred inspectors to conduct routine retail food facility inspection programs. California law does not currently provide for routine on-farm inspections for good agricultural practices or food safety by CDHS. The Department of Health Services conducts site visits and investigations when farms are implicated as the source in foodborne illness.

Question 2. Fresh lettuce and spinach grown and processed in the Salinas in California has been linked to 8 of the last 19 *E. coli* outbreaks that have occurred since 1995. Given your States interest in maintaining a robust national market for your agricultural products what additional measures are you considering to ensure continued consumer confidence? Have your colleagues at the national level been adequately engaged in these efforts?

Answer 2. The best way to ensure consumer confidence in California produce is for California to produce safe products that do not cause foodborne illness. To produce that safer product, we need a system that ensures that all farms are utilizing an enforceable, standardized, and verifiable set of scientifically-based good agricultural practices, and that the practices are adhered to 100 percent of the time. California agriculture has proposed a program that includes mandatory implementation of standardized good agricultural practices under a "Marketing Order" process identified in both Federal and State law, and independently verified under the California Department of Food and Agriculture.

Question 3. In your experience, was the response to the outbreak by the FDA and the CDC sufficiently robust? Did they have adequate numbers of inspectors and investigators to monitor and respond to the crisis?

Answer 3. The Federal response to this outbreak was rapid and well coordinated. CDC and FDA teamed up to conduct a national teleconference as soon as evidence of a multi-state outbreak was determined, and maintained that excellent communication with State health officials throughout the investigation. On the same day that the initial notification was made, CDHS met with FDA and planned the Food Emergency Response Team (Cal-FERT) strategy for investigating in the Salinas Valley. FDA and CDHS members of the Cal-FERT team traveled to Salinas that evening to start the investigation onsite. FDA and CDHS together contacted the processing firm and worked in very close partnership throughout the investigation. The team investigation in California serves as a national model for State-Federal cooperation and success in response to foodborne illness.

Question 4. Does California have the authority to issue a mandatory recall of produce grown or processed in California?

Answer 4. No. State law does not authorize CDHS to issue a mandatory recall.

Question 5. You testified at the hearing that "the Salinas Valley appears to have systemic *E. coli* O157:H7 contamination in the environment that has lead to a number of fresh produce associated outbreaks over time." The beef industry in its zero tolerance efforts to reduce *E. coli* contamination uses a "test and hold" procedure whereby a meat product is held while tests for the presence of *E. coli* O157:H7 are conducted. Does California possess the authority to require "test and hold" procedures to assure that fresh produce is safe to eat?

Answer 5. CDHS does not have specific statutes requiring a test and hold process for fresh produce. Growers and processors are required to do what is necessary to produce a safe product. We believe that we can never test our way to food safety. Testing is an important tool, but to provide safer fresh produce, we must have a system that ensures that *all* farms are utilizing an enforceable, standardized, and verifiable set of scientifically-based good agricultural practices, and that the practices are adhered to 100 percent of the time.

Question 6. In January of this year the California Department of Health Services sent a letter to the Western Growers Association. This letter highlighted the concerns raised by FDA in their November letter. In addition your department stated they were considering additional measures including the potential need for additional statues or regulations that include mandatory Good Agricultural Practices and/or mandatory Hazardous Analysis Critical Control Points for fresh cut produce. In light of the continued outbreaks are these measures likely to be implemented?

Answer 6. It is important that these measures be integrated into scientifically-based good agricultural practices that must be implemented in California.

Question 7. In light of the increasing number of outbreaks the Center for Science in the Public Interest has petitioned California to develop and implement mandatory and not voluntary compliance guidelines for growers and processors. Can you update this committee on your department's consideration of that petition?

Answer 7. CDHS is working closely with the industry and the California Department of Food and Agriculture to develop a requirement for producers to follow standardized good agricultural practices under the auspices of a marketing order.

Question 8. You testified that the fields that were the source of the contaminated spinach remain "disked under." Was this a voluntary action by the farmers or was this mandated by the FDA or by California? What is the role of the California Department of Health Services in determining if produce from these fields should/can be allowed to be reintroduced into the Nation's food supply? Does California possess the authority to prevent these fields from returning to production if nothing is done to address the concerns of contamination?

Answer 8. Two of the four owners of implicated farms voluntarily disked under produce growing on the implicated fields. The other two fields were barren and continue to have no fresh, ready to eat products planted. CDHS in partnership with FDA will evaluate the investigation findings and determine what the next steps will be with the implicated farms. State law provides CDHS with product embargo authority to prevent contaminated or adulterated products from entering commerce.

RESPONSE TO QUESTIONS OF SENATOR ENZI BY ROBERT WHITAKER, PH.D.

Question 1. There is a history of outbreaks of foodborne illness traced to produce grown in California's Salinas Valley dating back to 1995. Why is this area so susceptible to *E.coli* contamination?

Answer 1. First, we do not know scientifically that the Salinas Valley is more susceptible to *E.coli* contamination than any other area where leafy green produce is grown. In fact, State and Federal investigations following the outbreaks since 1995 in this area have not definitively indicated what the source of the contamination has been. What has been stated publicly by some is speculation based on assumptions and not what the scientific investigations have revealed. This has placed a tremendous amount of pressure on the fresh produce industry to prevent future outbreaks without knowing the sources of previous contamination. It is one of the major reasons I call on Congress in my testimony for increased dedication and resources to fresh produce food safety.

However, what we do know is that urban encroachment and certain environmental rules related to waterways and riparian areas encourage feral and domestic animals near the fields in Salinas. Whether this has actually contributed to the con-

tamination resulting in outbreaks is unknown, but the industry is focusing a tremendous amount of resources inspecting, monitoring, and correcting for animal activity.

Question 2. How is prepackaged produce washed? Does this process remove *E.coli* from green leafy produce?

Answer 2. The washing process is one of the best researched and scientifically supported points of the leafy greens process. Details will vary from company to company, but the washing process is generally as follows: first, leafy greens are trimmed, either in the field or in the processing plant, to remove obvious signs of dirt and decay. Large leafy greens, like iceberg and Romaine lettuce, may be mechanically chopped to salad sized pieces just prior to washing. The first wash of a "triple wash" process removes remaining surface dirt from the field. The greens are then removed from the first bath and transferred into a second, separate bath that contains a disinfectant chemical, like chlorine. The disinfectant level is a key component of the in-plant food safety system and is actively monitored. The leafy greens are agitated in both baths, like clothes are in a washing machine, to further "scrub" the greens. The greens are removed from this second bath and either put through a third bath or showered with microbially-disinfected water, before being shaken or spun dry and packaged. The triple wash process is most often automated, with little if any human contact, and has been optimized to be more controlled and effective than what consumers or foodservice operators could do in a kitchen.

Chemical disinfectants commonly used in wash water include chlorine compounds such as hypochlorite or chlorine dioxide, peracetic acid, ozone and others. Properly used, the disinfectant in the wash water is very effective at destroying bacteria like *E.coli* O157:H7 or Salmonella, when the bacteria are exposed on the produce or floating in the wash water, and so is very effective at preventing cross-contamination from leaf to leaf. However, all of these chemical disinfectants only eliminate 90–99 percent of the bacteria on the produce itself. Surviving bacteria are thought to be protected from the disinfectants by "hiding" in crevices, under waxy plant layers or biofilms, or internalized through cuts where the disinfectant cannot reach. That is why washing cannot be relied on as a kill step, like pasteurization.

Question 3. Your testimony indicated that washing in chlorinated water is not a "kill step" for spinach. I hope that we could always prevent *E.coli* contamination, but if we can't, is there anything on the horizon that would be a good kill step for spinach? What do you see as holding the most promise for reducing and containing outbreaks of foodborne illness associated with fresh produce?

Answer 3. We encourage a bimodal approach to food safety research. First we immediately need investment in research examining ways to prevent contamination from occurring throughout the supply chain. However, to your point, we must encourage researchers to continue to investigate technologies that can provide an adequate kill step for fresh produce and still retain the high quality and health benefits that consumers demand in these commodities.

For example, USDA has developed a steaming process that eliminates surface contamination on melons while retaining the quality of the product. At the same time, researchers across the country are exploring the use of irradiation. Unfortunately, neither of these processes has yet proven viable for leafy greens. Again, as my testimony has stated, a strong and robust research agenda for fresh produce is an immediate area where Congress and the Federal Government can help the fresh produce industry overcome the many challenges you have highlighted in your questions.

Response to Questions of Senator Enzi by Terri-Anne Crawford

Before I answer the questions below, I'd like to give a high level overview of RFID technologies, which will help frame the responses by giving a general knowledge of RFID for the audience.

Auto Identification (Auto-ID) is the broad term given to a host of technologies that are used to help machines identify objects. Some of the technologies that fall under the Auto Identification (Auto-ID) umbrella include bar codes, smart cards, voice recognition, some biometric technologies (retinal scans, for instance), optical character recognition, and radio frequency identification (RFID). Auto-ID is often coupled with automatic data capture. That is, companies want to identify items, capture information about them and somehow get the data into a computer without having employees type it in. The aim of most Auto-ID systems is to increase efficiency, reduce data entry errors, and free up staff to perform more value-added functions.

RFID is a generic term for technologies that use radio waves to transfer data. RFID technology consists of 2 basic components, an RFID tag or transponder and

an RFID reader or scanner. An RFID tag can be applied to almost any entity and then can be used to identify that entity.

RFID readers or scanners are a proximity reader, which means they do not require contact between the reader and the tagged entity. This ability to read the information from the tags without line-of-sight or direct contact is the primary advantage of RFID tags for identifying product or other entities. The bar code's biggest shortcoming is that it is a line-of-sight technology. That is, a scanner has to "see" the bar code to read it, which means people have to orient the bar code towards a scanner for it to be read. RFID tags can be read as long as they are within range of a reader. Also, standard bar codes identify only the manufacturer and product, not the unique entity. The bar code on one milk carton is the same as every other carton from the same manufacturer, making it impossible to identify which carton might pass its expiration date first or to track the exact path or location of a particular carton within the supply chain.

There are several methods of identifying objects using RFID, but the most common is to store a serial number that identifies a product and perhaps other information, on a microchip that is attached to an antenna (the chip and the antenna together are called an RFID transponder or an RFID tag). The antenna enables the chip to transmit the identification information to a reader. The reader converts the radio waves returned from the RFID tag into a form that can then be passed to computers that can make use of it.

There are 3 different types of RFID tags, all function a bit differently and with different read range capabilities. There are active tags, semi-passive and passive tags.

- Passive RFID tags have no internal power supply. They rely on the current generated from received radio signals to power and transmit a response; therefore they are not capable of continually transmitting data. Passive tags have a read distance ranging from about 4 inches to 15 feet depending upon radio frequency and antenna used. Passive tags are the least expensive tags, due to not having a power source on-board.
- Semi-Passive RFID tags have batteries to run the chip circuit so that the tags are constantly powered. However, they still need power from incoming radio signals to transmit a response.
- Active RFID tags also known as beacons have their own internal power source which is used to power the integrated circuit and generate the outgoing signal. Instead of just responding to incoming signal from the reader they can broadcast their own signal at regular intervals of time. Active tags have a longer range of up to 300 feet

The Electronic Product Code (EPC) is a new product numbering standard under development by a division of GS1 (*www.gs1.org*) that can be used to detect, track, and control a variety of items using RFID technology. GS1 is the most implemented system of supply chain standards in the world. The EPC links to an online database and provides a secure way of sharing product-specific information throughout the supply chain. Basically, the EPC is a standard for product "license plates." The primary difference between today's standard product bar code and the EPC is that the bar code identifies a unique product and the EPC contains additional information (serialization) that distinguishes each individual occurrence of that product. This is the difference between a computer just knowing that the product is a carton of Coca-Cola and knowing the distinct carton of Coke and information about that carton, such as it's lot number, manufacture date, expiration date and any place it has traveled through the supply chain.

EPCglobal (*www.epcglobalinc.org*) is a product area or division of GS1 and is a member-driven organization leading the development of standards for the EPC and the EPC Network to support the use of radio frequency identification (RFID) in trading networks.

Like other RFID solutions, the EPC has the ability to be read without a clear line-of-sight scan. Another advantage is the ability to update information automatically from the EPC into supply chain logistics applications. Warehouse and store receiving and inventory applications should benefit from this advantage. Benefits include allowing information about a particular entity to be easily read and transferred to computerized business applications resulting in increased efficiency and a reduction in data entry errors.

I believe there is some confusion when people begin to talk about using RFID for track and trace of products in the supply chain. The idea is not to actually use the RFID chip, continually transmitting, to track exactly where each bag of spinach or gallon of milk is currently located, but rather to exploit the usability and readability of these tags, with a vast network of readers to monitor where the product travels

and record a breadcrumb trail of the life of a product. Therefore, when it is said that we can know where the product is within the supply chain, what it really implies is that we can assume where the product is based on the last time it was read and updated to a computer system.

In my testimony, when I refer to tracking the product, it is through computer systems and readers, which would need to be deployed throughout the supply chain to capture the information and update it to a network that can be accessed by those that need the information, manufacturer, wholesalers, retailers and even government agencies in the case of product recall. This was the idea from MIT when the EPC Network was conceptualized. The vision is to have a shared network, which knows information about products and is easily accessible to all that need the information.

It comes down to 2 main issues. First, there needs to be a shared network which contains all the information about product flows to build a breadcrumb trail or pedigree of where a particular product has been and where it currently resides within the supply chain. Second, each case or package of the product has to have its own identification so that it can be distinguished from other cases or packages of the same product. The EPC code, with serialized RFID tags and the EPC Network are the keys to overcoming this challenge.

Question 1. You mentioned in your testimony that it would be too expensive for RFID to tag each bag of spinach. How then could you use RFID to trace fresh produce, given that produce is so perishable and the packaging quickly discarded by consumers?

Answer 1. Thank you for the opportunity to clarify this issue. First I would like to say, that at readily available prices for RFID tags (around $.15 to $.20), it would be cost prohibitive to tag each bag of spinach or any other individual packages of produce. But it is also true that the price of tags is driven by the cost of manufacturing, which in turn is influenced by volume, so if higher volumes of product are being tagged, the prices of the tags will drop significantly. As RFID tagging is more widely adopted, it is conceivable that eventually it will be cost effective to tag most products at the item level.

The tracing of fresh produce that I spoke about, is intended for the supply chain trading partners, suppliers and retailers. Tagging the product as it is processed or manufactured and using the computer systems and readers to build a breadcrumb trail of a product's journey through the supply chain and to capture the trail on a shared network, all the way to the store. Since it relies on the network of computers and readers to keep track of the product, it is neither conceivable nor intended to track it to individual consumers. Product in a consumer's home would still need to be manually verified by the consumer through human readable lot numbers and/or other identification on the package.

But with improved tracking throughout the supply chain and the ability to follow the path of the product, the shared network can be used to determine where all products from a particular source went, and then the communication to the consumer could be much more accurate and timely. For example, if this level of tracking existed (even just for the case of bagged spinach and not each individual bag) once the source of the problem is discovered it could be determined the distribution path of that product in its entirety. If the tainted product did not make it into certain regions, States, cities or retail outlets, then the product in those areas can quickly be identified as safe and this information can be communicated to the consumers. The converse is also true, providing the capability to communicate with the consumers in certain regions or that shopped with certain retailers that their product may have an issue.

Question 2. Although I see a lot of potential for RFID, I am a bit concerned about the idea of a tag on my food that can transmit information—I think anyone who values their privacy would be. Does the RFID tag tracing end at the time the product is purchased or does it follow the customer home? What is the distance range of the transmission? How can privacy concerns be addressed?

Answer 2. In the information age, privacy, rightfully so, is always a concern. GS1/EPCglobal is developing a standard for deactivating or killing a tag at customer checkout. EPCglobal will also work with the member companies, suppliers and retailers, to educate consumers about this feature. But even without this feature, recall my explanation above about readers being required to access the tags, therefore the tracing basically ends at the time of purchase. The tags that will be used for tracking product through the EPC are passive tags, which have a read range of 4 inches to 15 feet and are not capable of transmitting data without being powered by a reader.

Question 3. Given that there are a number of RFID manufacturers, software developers and end users, can you comment on the need for and progress toward interoperability of these tracking systems to ensure that we get value out of this technology?

Answer 3. As I stressed in my testimony, standards and interoperability are critical. RFID manufactures and software developers recognize this need and most, if not all, are involved with GS1/EPCglobal which is the international standards body for the Electronic Product Code (EPC) and the EPC Network. GS1 is the same body that governs the use of bar codes and the product numbering standards for bar codes. I believe that industry has learned from the implementation of bar codes that standards and interoperability are a must.

RESPONSE TO QUESTIONS OF SENATOR ENZI BY JEFF PALMER

Question 1. You indicated that you had tried to get an SBIR grant to assist in the development of the Timestrip technology, but were unsuccessful. What other barriers do you see to the development of new food safety technologies by small businesses?

Answer 1. We established contact with the Ohio Department of Development in hopes of securing some support for the continued research & development of the timestrip technology. During our meeting with our State development representatives, we were told at the time that this particular technology did not meet with the definitions of available funding through the Ohio 3rd Frontier program, which was established to expand on technology advancement within Ohio. We have been successful in getting some tax savings for our R&D efforts. In terms of barriers, we do see the constant need for education and awareness building at least as an ongoing challenge—if not a barrier—so that the industry can ensure that decisionmakers have a full understanding of the issues, needs, trends and solutions present in the industry. Without universal knowledge, it'll certainly be tougher to further technologies.

Question 2. Given the current number of foodborne illnesses and the way they occur, what is the food service industry and government doing or not doing to contribute to reducing those statistics? What more do you think can be done to reduce the incidence of foodborne illness?

Answer 2. Currently inspectors are auditing restaurants and record and/or fine owners for health code violations. The work being done by your Senate subcommittee will continue to help make food safety, and measures designed to prevent or control the incidence of foodborne illness, a top-of-mind agenda item among policymakers. Also, more and improved ways of training (such as DayMark's Certified Safer online training program) foodservice staff so that best practices are consistently followed and better methods are learned, forums for industry food safety symposia, and the offering of innovative products from companies like DayMark—all these things will help curb the problem.

RESPONSE TO QUESTIONS OF SENATOR ENZI BY JOHN VAZZANA

Question 1. Bacteriophage sounds like a really amazing technology. However, I think people may be put off by the idea that their food has been sprayed with a virus. Are you worried about consumer acceptance of LMP-102? What are you doing to reach out to consumers to explain the use and value of your product?

Answer 1. We are very concerned about consumer reaction to LMP-102. Today, most Americans believe there are good bacteria and bad bacteria. The challenge to Intralytix is to convince the average consumer that there are good viruses. We have the science on our side, but that is not necessarily enough. It is very interesting that the most vocal opponents of our technology see our technology as a quick fix for industry. They believe good manufacturing practices will be sufficient to solve the Listeria problem. Unfortunately, this is not true. We are taking the following steps:

a. We are seeking large corporations to sell and market the product on a national basis. We need these companies to commit significant funds for consumer education.

b. We are scaling up manufacturing, and intend to send samples to potential users in the first quarter. We have been contacted by 70 ready to eat producers who have expressed an interest in our product. Most of these companies have had a serious problem with Listeria, and the benefits outweigh the potential customer acceptance issues. None of these companies are the large multinational producers.

Question 2. What are the obstacles to further development of phages technology for food safety uses?

Answer 2. The other obstacles are:

a. Money is always a problem in the development of new products, but the costs to develop new phages products are relatively low.

b. Upon approval of LMP-102, USDA took the position that any product treated with LMP-102 must show LMP as an ingredient on the label. The large producers are opposed to this. They fear groups opposed to LMP-102 will target their products. USDA believes LMP-102 must be on the label because of the residual effect of the product. LMP-102 will dissipate over time if Listeria is not present. Because most ready to eat foods are refrigerated after packaging, the phage will still be present when the consumer opens the package. This is called a residual effect. As I mentioned in my presentation, phages are absolutely harmless, and we all consume millions of phages daily. The interesting fact is that if Listeria is present in the home when the package is opened, LMP will protect the food treated with LMP.

Question 3. You indicate that you would prefer to receive FDA approval under the food contact substance notification process, rather than the food additive process as you did for LMP-102 because the food additive process takes a long time. Why are phage products currently considered food additives? What is the basis for this classification?

Answer 3. Thank you again for the opportunity to present information to the committee about Intralytix, Inc., and the products we are developing at our facility in Baltimore, MD, to improve food safety. The first product we developed to enhance food safety, LMP-102, is a dilute buffered aqueous solution that includes six bacteriophage (phage) which are viruses that are specific to bacteria. In the case of LMP-102, the phage are specific to Listeria, including the pathogenic species Listeria monocytogenes; it took over 4 years to obtain approval from the Food and Drug Administration (FDA) for this product utilizing the food additive petition process. The next product for which we will be seeking clearance is called ECP-100; it targets the deadly bacteria *E. coli* O157:H7. Vegetable growers, packers and consumers cannot afford to wait 4 years to gain access to the public health protection ECP-100 will provide. To accelerate clearance of our second phage-based food safety product, Intralytix intends to utilize the notification mechanism for food contact substances that Congress wisely added to the Federal Food, Drug, and Cosmetic Act (the act) in 1997 as section 409(h). 21 U.S.C. 348(h). If FDA agrees to review the ECP-100 under the Food Contact Notification (FCN) scheme, ECP-100 could be authorized for sale and available to contribute to the protection of public health after a 120-day notification period. As part of the food contact notification legislation, FDA was given the authority to determine that the notification process is not appropriate in a particular case and to require that clearance be sought by the more time-consuming petition process. Intralytix would greatly appreciate it if you and others on the committee expressed to FDA your support for the use of the notification process with regard to ECP-100.

DESCRIPTION OF ECP-100

ECP-100 is a bacteriophage preparation that has been developed to selectively attack the deadly *E. coli* strain O157:H7, which was the contaminant in the recent nationwide spinach recall incident and resulted in numerous illnesses and several fatalities. As I have previously described to the committee, by mass, the amount of phage in ECP-100 is truly trivial. Indeed almost the entire mass of ECP-100 is water. ECP-100 is applied directly to the surface of the food immediately before packaging. If the food is not contaminated by *E. coli*, the phage preparation does nothing other than moisten the surface of the food. If *E. coli* is present, the phage infects the bacteria, multiplies and spreads to eradicate the contamination. FDA thoroughly documented the safety of phage preparations in the preamble to the food additive regulation responsive to a petition filed by Intralytix with regard to LMP-102. 71 Fed. Reg. 47729 (August 18, 2006). It has also indicated that it has no objection to GRAS (generally recognized as safe) Notification #198 submitted by EBI Food Safety with respect to a listeria phage for use on cheese.

REGULATORY PROCEDURE FOR OBTAINING FDA'S APPROVAL

The FCN procedure provides a streamlined approval process by which a manufacturer notifies FDA of its intent to market a "food contact substance," which is defined as a substance "intended for use as a component of materials used in the manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food." See § 409(h)(6) of the Act; 21 U.S.C. § 348(h)(6). While the primary intent of this clearance option was intended to be, and has been tremendously successful as applied to, packaging materials, the term "food contact substance" as defined is much broader than just packaging.

We believe ECP-100 is eligible for clearance under this expedited process because it will be used in contact with food during packing or packaging operations and it has no technical effect on the food. ECP-100 does not alter the nutritional value of food; it does not alter taste, color or aroma; it does not texturize; it does not even preserve or otherwise extend the shelf life of food since it has no effect on spoilage organisms. For sure, ECP-100 protects food from a pathogenic organism, but it does so without affecting the food. ECP-100's one and only effect is to eradicate the deadly non-food *E. coli* O157:H7 bacteria should it happen to be present. Very much like food packaging, ECP-100 protects food from contamination without otherwise affecting the food. Stated differently, its only effect is to effect safety.

Although Intralytix expects to be the first to submit an FCN for a phage preparation, FDA already has a well established practice of utilizing the FCN process to clear antimicrobials that are much more broadly effective than phage. Indeed, FDA has previously agreed to rely on the FCN procedure to clear antimicrobials on at least nine occasions. In all of these cases, the antimicrobial agent is applied directly to the surface of food or to water in which the potentially contaminated food will be washed.[1] In sum, it is our position that the FCN procedure is an appropriate procedure by which to request FDA's clearance of ECP-100.

Under the FCN procedure, the manufacturer provides FDA with data and documentation identifying the substance, its intended use, and information that forms the basis of the manufacturer's determination that the intended use of the substance is safe. After all of the requisite information is provided to FDA, the Agency has 120 days to review the materials, and if the Agency has no objections, it posts a notice on its Website (*www.cfsan.fda.gov/~dms/opafcn.html#invt*) indicating that the FCN is "effective" and that the substance is cleared for use on food subject to any noted restrictions or limitations. With the experience gained by both Intralytix and FDA's Center for Food Safety and Applied Nutrition, we are optimistic that 120 days will be more than adequate for FDA to evaluate Intralytix' ECP-100 submission.

FDA SHOULD BE ENCOURAGED TO FAVORABLY REVIEW THE FCN FOR ECP-100

E. coli O157:H7 is a deadly bacteria that has already claimed the lives of many innocent people. ECP-100 was developed specifically to target *E. coli* O157:H7, and it is not only highly effective, but also exceedingly safe because phage are effective only against bacteria. Its use on food will save lives, and as such, its safety and proposed use on food should be reviewed as soon as possible by FDA. Since the FCN procedure is the least time-consuming avenue for obtaining the Agency's approval, and since many other antimicrobial substances already have been reviewed by FDA via the FCN procedure, your encouragement that FDA favorably consider our FCN submission so as to permit our Nation's food supply to be protected from the deadly *E. coli* O157:H7 as soon as possible will be greatly appreciated.

[Whereupon, at 5:25 p.m., the hearing was adjourned.]

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[1] For example, FCN #35 clears dimethyl dicarbonate for use as a microbial control agent in non-carbonated juice beverages containing up to and including 100 percent juice; FCN #140 clears a mixture of peroxyacetic acid, acetic acid, hydrogen peroxide, and 1-hydroxyethylidene-1, 1-diphosphonic acid (HEDP) for use as an antimicrobial agent for red meat carcasses; FCN #295 clears hydrogen peroxide for use as a component of an antimicrobial formulation for use on poultry carcasses, poultry parts, and whole and cut raw fruits and vegetables; FCN #296 clears the use of silver nitrate for use as a component of an antimicrobial formulation for use on poultry carcasses, poultry parts, and whole and cut raw fruits and vegetables; FCN #323 clears a mixture of peroxyacetic acid, hydrogen peroxide, acetic acid, 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP), and water for use as an antimicrobial agent for meat and poultry carcasses; FCN #453 clears 1,3-dibromo-5,5-dimethylhydantoin for general use as an antimicrobial agent in water used in poultry processing for disinfecting poultry carcasses and their parts and organs (essentially superceding FCNs #334 & 357 which cleared narrower uses in poultry processing; FCN #445 clears chlorine dioxide as an antimicrobial agent in water used in poultry processing and to wash fruits and vegetables that are not raw agricultural commodities; and FCN #450 clears a mixture of sodium chlorite and chlorine dioxide as an antimicrobial agent in the processing of red meat, red meat parts and organs, and on processed, comminuted, and formed meat products as a component of a dip or a spray.